Registration Jacket 55541-2 Volume 3

Ms. Cristina Griffin Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904

OCT 29 2012

Subject:

Counter Assault; Counter Assault Bear Deterrent, EPA Registration No. 55541-2; Amendment to Eliminate Alternate CSF, and to Correct Active Ingredient Name and Spray Time Claim; D# 466562, Application Dated 6/27/12

Dear Ms. Griffin:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A), is acceptable provided that you:

- Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- Submit two (2) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(b). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions contact Chris Pfeifer at 703-308-0031 or by email at: pfeifer.chris@epa.gov. A stamped copy of the label is enclosed for your records.

Sincerely,

Linda A. Hollis, Chief

Biochemical Pesticides Branch

Biopesticides and Pollution

Prevention Division (7511P)

Enclosure

			CONCURRENC	ES .			
SYMBOL >	7511P						
SURNAME >	PFEIFER						
DATE	10/18/12						
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PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals DANGER:

May cause irreversible eye damage if sprayed in the eye at close range. Contact through touching or rubbing eyes may result in substantial but temporary eye injury. Strongly irritating to nose and skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing eye. Call poison control center or doctor for treatment advice. Have product container with you when calling or going for treatment. For emergency medical treatment information call 1-800-535-5053.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor immediately for treatment advice.

PHYSICAL OR CHEMICAL HAZARDS:

Extremely flammable. Contents under pressure. Keep away from fire, sparks and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

STORAGE & DISPOSAL

STORAGE: STORE IN A COOL DRY PLACE INACCESSIBLE TO CHILDREN AND PETS. Do not store in places where the temperature is above 120°F nor below 32°F. Do not store in hot vehicle or in direct sunlight.

DISPOSAL: DO NOT PUNCTURE OR INCINERATE! Non-Refillable Container. Do not reuse or refill this container.

If empty: Press valve to release all pressure then place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions.

Disclaimer: To the extent allowable by law, Counter Assault shall not be liable for damage, injury, loss, direct or consequential including death arising out of the use of, or inability to use this product.



KEEP OUT OF REACH OF CHILDREN DANGER

DO NOT SEEK OUT ENCOUNTERS WITH BEARS. THIS PRODUCT IS A BEAR ATTACK DETERRENT WHICH MAY PROTECT USERS IN SOME UNEXPECTED CONFRONTATIONS WITH BEARS BUT MAY NOT BE EFFECTIVE IN ALL SITUATIONS OR PREVENT ALL INJURIES. READ THIS ENTIRE LABEL BEFORE TAKING THIS PRODUCT INTO AREAS WHERE BEARS MIGHT BE ENCOUNTERED. SEE SIDE PANELS FOR FIRST AID AND PRECAUTIONARY STATEMENTS.

Active Ingredient:

Capsaicin and related capsaicinoids* 2.0%
Other Ingredients 98.0%
TOTAL 100.0%

*Derived from Oleoresin of Capsicum

Manufactured by:
Bushwacker Backpack and Supply Co., Inc.
dba COUNTER ASSAULT
120 Industrial Court, Kalispell, MT 59901
1-800-695-3394 • (406) 257-4740
CHEMICAL EMERGENCY: 1-800-535-5053

NET CONTENTS: 8.1 ounces (230g)

EPA Registration #55541-2

EPA Est No: 055541-MT-001

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used only to deter bears which are attacking or appear likely to attack humans. Do not spray this product on objects, tents, or humans; such use has no deterrent effect on bears. Do not seek out encounters with bears or intentionally provoke them. Keep safety clip in place except when practicing with or using the product. Do not eat or allow to be eaten any food or feed materials which may have become contaminated with this product.

This product has a range of up to 30 feet (9 meters). The canister empties in approximately 7 seconds.

APPLICATION DIRECTIONS: Special procedures must be followed to arm the container, apply the product and restore the safety clip to disarm the container. Before taking this product into bear country, read the directions below and familiarize yourself with these procedures. If you test-fire this container, make sure the wind is at your back and depress actuator tab for no more than half a second. Do not test-fire in area inhabited by bears. If test-fired, clean nozzle and can with soap and water to remove residue from can. If you have not used this product before, you should obtain a Counter Assault training can and practice with it until you can perform these activities quickly and accurately.

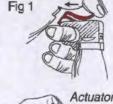
To Arm and Apply

Designed for one-hand operation. Place forefinger through hole in handle with thumb on safety clip curl. With thumb, pull safety clip straight back and off (fig 1).

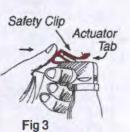
Depress actuator tab for burst of spray (fig 2). Aim at face and eyes of bear. Depress actuator tab for 1-2 seconds in order to create a barrier of spray between you and the bear. Stop to evaluate the impact of wind and other factors and adjust your aim if needed before spraying again.

To Disarm

Replace safety clip by pushing firmly with thumb until audible 'snap' is heard (fig 3). Check to see if safety is completely in place. No gap should be visible between actuator handle and safety clip.







Grizzly Tough" Bear Spray

Works on all bear species to deter bears from attacking humans



Developer of high emission "atomized" fire extinguisher-style spray used in bear deterrents.





Glow in the dark safety wedge with tie string

Sprays to 30 feet; 7 seconds of spray time (230g)

Produced by a Grizzly Bear Encounter Survivor!

(story on reverse)





In the early 1980's, bear biologists were researching effective bear deterrents. The result of this research was the development of an atomized spray and led to the creation of Counter Assault.

Pride Johnson, President & Chemist of Counter Assault successfully survived a grizzly encounter with Counter Assault Bear Deterrent. The encounter was immediately stopped.

DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used only to deter bears which are attacking or appear likely to attack humans. Do not spray this product on objects, tents, or humans; such use has no deterrent effect on bears. Do not seek out encounters with bears or intentionally provoke them. Keep safety dip in place except when practicing with or using the product. Do not eat or alliow to be eaten any food or feed materials which may have become contaminated with this product.

This product (230g canister) has a range of up to 30 feet (9 meters). The canister empties in approximately 7 seconds.

APPLICATION DIRECTIONS: Special procedures must be followed to arm the container, apply the product and restore the safety clip to disarm the container, Before taking this product into bear country, read the directions below and familiarize yourself with these procedures. If you test-fire this container, make sure the wind is at your back and depress actuator tab for no more than half a second. Do not test-fire in area inhabited by bears.

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TO DISARM: Replace safety clip by pushing firmly with thumb until audible "snap" is heard (lig 3), Chack to see if safety is completely in place. No gap should be visible between actuator handle and safety clip.



DANGER: May cause irreversible eye damage if sprayed in the eye at close range, Confuct through touching or rubbing eyes may result in substantial but temporary eye injury. Strongly irritating to nose and skin, Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID: IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing eye. Call poison control center or doctor for treatment advice. Have product container with you when calling or going for treatment. For emergency medical treatment information call 1-800-535-5053.

IF ON SIGN OR CLOTHING: Take off contaminated clothing. Rinse skin invited lately with plenty of water for 15-20 minutes. Call poison control center or doctor immediately for treatment advice.

PNYSICAL OR CHEMICAL MAZARDS:Extremely flammable. Contents under pressure. Keep away from fire, sparks and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

STORAGE & DISPOSAL

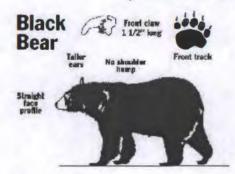
STORAGE: STORE IN A COOL DRY PLACE INACCESSIBLE TO CHILDREN AND PETS, Do not store in places where the temperature is above 120°F nor below 32°F. Do not store in not vehicle or in direct suplicity.

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Know Your Bears

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Bear Short rounded cars Shoulder hump Front truch

Item# CA12H/s

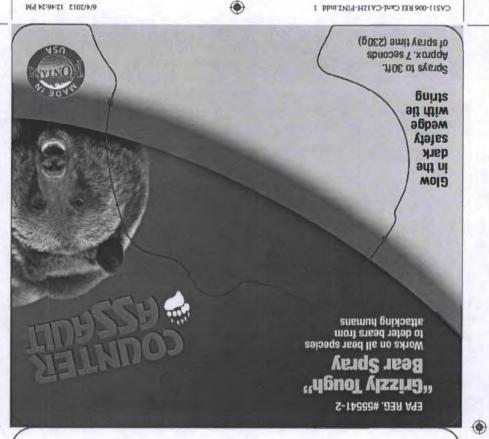
Fig. 3

NET CONTENTS: 8.1 ounces (230g)

Questions or comments: answers-info@counterassault.com

Manufactured by:
Bushwacker Backpack and Supply Co., Inc.,
dba COUNTER ASSAULT
120 Industrial Court, Kalispell, MT 59901
1-800-695-3394 • (406) 257-4740
CHEMICAL EMERGENCY

1-800-535-5053





Produced by a Grizzly Bear Encounter Survivor

In the early 1980's, bear biologists were researching effective bear deterrents. The result of this research was the development of an atomized spray and led to the creation of Counter Assault.

Pride Johnson, President & Chemist of Counter Assault successfully survived a grizzly encounter with Counter Assault Bear Deterrent. The encounter was immediately stopped.



Counter Assault Bear Deterrent:

- · Developed in conjunction with the University of Montana
- Developer of high emission "Atomized" fire extinguisher-style spray used in bear deterrents

Manufactured by: Bushwacker Backpack and Supply Co., Inc. dba COUNTER ASSAULT 120 Industrial Court, Kalispell, MT 59901 1-800-695-3394 • (406) 257-4740 Questions or comments: answers-info@counterassault.com

> CHEMICAL EMERGENCY 1-800-535-5053

> > **NET CONTENTS: 8.1 ounces (230g)**



PRECAUTIONARY STATEMENTS ACCEPTED **Hazards to Humans and Domestic Animals** DANGER:

May cause irreversible eye damage if sprayed in the eye at close range. Contact through touching redenticide act or rubbing eyes may result in substantial the pesticide register. temporary eye injury. Strongly irritating to BRACKER. No. 555 and skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

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PHYSICAL OR CHEMICAL HAZARDS:

Contents Extremely flammable. under pressure. Keep away from fire, sparks and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

STORAGE & DISPOSAL

STORAGE: STORE IN A COOL DRY PLACE INACCESSIBLE TO CHILDREN AND PETS. Do not store in places where the temperature is above 120°F nor below 32°F. Do not store in hot vehicle or in direct sunlight.

DISPOSAL: DO NOT PUNCTURE OR INCINERATE! Non-Refillable Container. Do not reuse or refill this container.

If empty: Press valve to release all pressure then place in trash or ofter for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions.

Disclaimer: To the extent allowable by law. Counter Assault shall not be liable for damage. injury, loss, direct or consequential including death arising out of the use of, or inability to use this product.

BEAR DETERRENT
GRIZAN TOUGH PEPPER SPRAY
MAGNUM 290

NOT-

NOT FOR USE ON HUMANS

TO DETER BEARS FROM ATTACKING HUMANS

KEEP OUT OF REACH OF CHILDREN DANGER

DO NOT SEEK OUT ENCOUNTERS WITH BEARS. THIS PRODUCT IS A BEAR ATTACK DETERRENT WHICH MAY PROTECT USERS IN SOME UNEXPECTED CONFRONTATIONS WITH BEARS BUT MAY NOT BE EFFECTIVE IN ALL SITUATIONS OR PREVENT ALL INJURIES. READ THIS ENTIRE LABEL BEFORE TAKING THIS PRODUCT INTO AREAS WHERE BEARS MIGHT BE ENCOUNTERED. SEE SIDE PANELS FOR FIRST AID AND PRECAUTIONARY STATEMENTS.

Active Ingredient:

Capsaicin and related capsaicinoids* 2.0% Other Ingredients 98.0% TOTAL 100.0%

*Derived from Oleoresin of Capsicum

Manufactured by: Bushwacker Backpack and Supply Co., Inc. dba COUNTER ASSAULT 120 Industrial Court, Kalispell, MT 59901 1-800-695-3394 • (406) 257-4740 CHEMICAL EMERGENCY: 1-800-535-5053

NET CONTENTS: 10.2 ounces (290g)

EPA Registration #55541-2

EPA Est No: 055541-MT-001

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used only to deter bears which are attacking or appear likely to attack humans. Do not spray this product on objects, tents, or humans: such use has no deterrent effect on bears. Do not seek out encounters with bears or intentionally provoke them. Keep safety clip in place except when practicing with or using the product. Do not eat or allow to be eaten with food or feed materials which may have become contaminated with this product.

This product has a range of up to 32 feet (10 meters). The canister empties in approximately 9 seconds.

APPLICATION DIRECTIONS: Special procedures must be followed to arm the container, apply the product and restore the safety clip to disarm the container. Before taking this product into bear country, read the directions below and familiarize yourself with these procedures. If you test-fire this container, make sure the wind is at your back and depress actuator tab for no more than half a second. Do not test-fire in area inhabited by bears. If test-fired, clean nozzle and can with soap and water to remove residue from can. If you have not used this product before, you should obtain a Counter Assauft training can and practice with it until you can perform these activities quickly and accurately.

To Arm and Apply

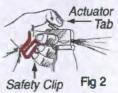
Designed for one-hand operation. Place forefinger through hole in handle with thumb on safety dip curl. With thumb, pull safety clip straight back and off (fig 1).

Depress actuator tab for burst of spray (fig 2). Aim at face and eyes of bear. Depress actuator tab for 1-2 seconds in order to create a barrier of spray between you and the bear. Stop to evaluate the impact of wind and other factors and adjust your aim if needed before spraying again.

To Disarm

Replace safety clip by pushing firmly with thumb until audible "snap" is heard (fig. 3). Check to see if safety is completely in place. No gap should be visible between actuator handle and safety clip.









Produced by a Grizzly Bear Encounter Survivor

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FIG. 2

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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This product (290g canister) has a range of up to 32 feet (10 meters). The canister empties in approximately 9 seconds.

APPLICATION DIRECTIONS: Special procedures must be followed to arm the container, apply the product and restore the safety clip to disarm the container. Before taking this product into bear country, read the directions below and familiarize yourself with these procedures. If you test-fire this container, make sure the wind is at your back and depress actuator tab for no more than half a second. Do not test-fire in area inhabited by bears, if test-fired, clean nozzle and can with seap and water to remove residue from can. If you have not used this product before, you should obtain a Counter Assault training can and practice with it until you can perform the activities quickly and accurately.

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DAMBER: May cause irreversible eye damage if sprayed in the eye at close range. Contact through touching or rubbing eyes may result in substantial but temporary eye injury. Strongly irritating to nose and skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with seap and water after handling. Remove contaminated clothing and wash clothing before reuse.

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Know Your Bears

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Item# CA18H/
Manufactured by:

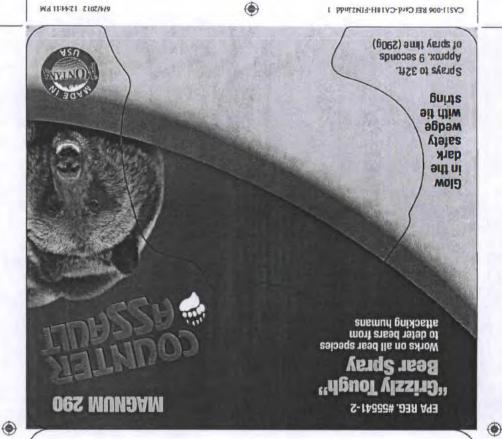
NET CONTENTS: 10.2 ounces (290g)

Questions or comments: answers-info@counterassault.com

Bushwacker Backpack and Supply Co., Inc. dba COUNTER ASSAULT 120 Industrial Court, Kalispell, MT 59901 1-800-695-3394 • (406) 257-4740 CHEMICAL EMERGENCY

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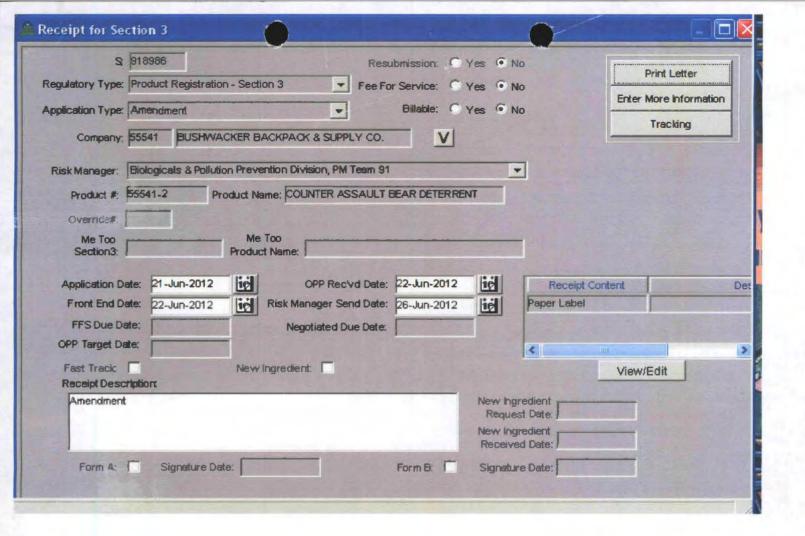
> CHEMICAL EMERGENCY 1-800-535-5053

Item# CA18/pb

NET CONTENTS: 10.2 ounces (290g)







Decory 2-12



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Prode

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

June 26, 2012

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

KIRSTEN K. JOHNSON BUSHWACKER BACKPACK & SUPPLY CO. D/B/A COUNTER ASSAULT 120 INDUSTRIAL COURT KALISPELL, MT 59901

PRODUCT NAME: COUNTER ASSAULT BEAR DETERRENT

COMPANY NAME: BUSHWACKER BACKPACK & SUPPLY CO.

OPP IDENTIFICATION NUMBER: EPA FILE SYMBOL: 55541-2 EPA RECEIPT DATE: 06/22/12

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 308-8733.

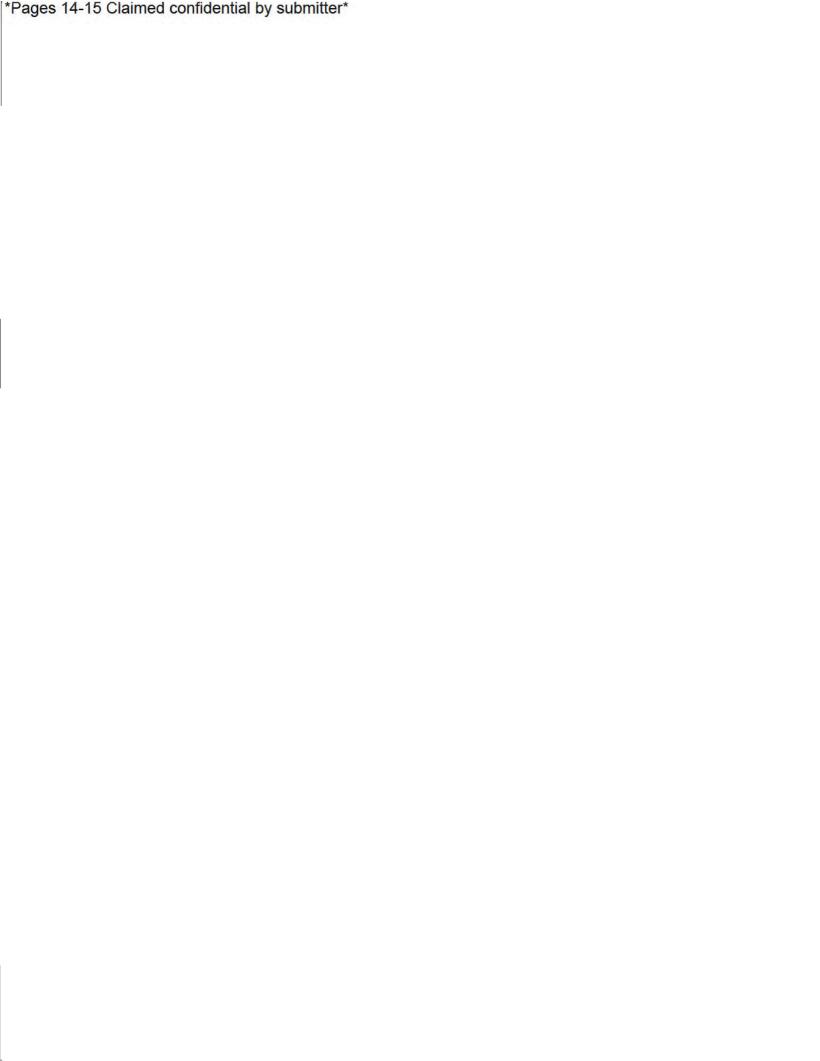
Sincerely,

Front End Processing Staff Information Services Branch

Information Technology & Resources Management Division

Fee for Service {918986g~

This package includes the following	for Division
New RegistrationAmendment	○ AD ◎ BPPD ○ RD
□ Studies? □ Fee Waiver? □ volpay % Reduction:	Risk Mgr. 91
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	918986 55541-2 6/22/2012
This item is NOT subject to Action Code: Requested: Granted: Amount Due: \$	o FFS action. Parent/Child Decisions:
Reviewer: Muleu Byce land	Uncleared Inert in Product Date: 6/26/12



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

November 6, 2007 E-Mail

Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904

Attention: Ms. Cristina Griffin

Subject: Counter Assault Bear Deterrent

EPA Reg. No. 55541-2

Your amended application of December 20, 2006

Your resubmission of October 11, 2007

Our telephone conversation of October 5, 1007

Purpose The purpose of your resubmission and telephone conversation is to clarify

the Spray Pattern Study Methodology before agreeing to a revised PRIA

Due Date of February 11, 2008.

Questions You had the following questions about the methodology of the spray

pattern test:

1. Change in Methodology and Review

You wanted to know if the Agency had changed its methodology and review of the spray pattern tests since Counter Assault had last submitted such data.

The EPA has not changed its methodology and review of such tests. It still requires that companies:

- test each can size
- record the spray pattern (height and width of spray cloud at specific distances of 10', 15', 20', 25', 30', and/or 35', etc), as appropriate for the product [See 10-24-2007 E-Mail from efficacy reviewer, previously received.]

Questionscontinued

- Record the total discharge time of spray (to the sensitivity of the timing device) from start to finish [Note: Spray time would not include the time when only propellant is discharged, but no spray.]
- record total number of 1 sec burst in one can
- repeat the test with additional cans [You plan to test 10 samples of each can. That is sufficient.]
- record temperature and wind speed and direction
- supply a video tape of the tests (optional).

2. Minimum or Average Spray Discharge Time/Distance

You were concerned that the EPA was now using minimum, rather than average, spray discharge time and spray discharge time in its review of the data. Counter Assault was concerned that such a change would put Counter Assault at a competitive disadvantage if we used average values for the evaluation of competitors and minimum values for the evaluation of Counter Assault.

EPA has consistently considered minimum values to be the operative values for spray time and spray distance. A review of our past approvals for this product shows that we conditioned our acceptance of your labeling in July 2004 (copy attached) to include changing the discharge time from 9.2 to 9 seconds for the larger can and from 7.2 to 7 seconds for the smaller can. In a later approval (November 2004), you included the incorrect values, which we overlooked. At your next printing, you need to make these changes to your labeling and submit revised labeling to us for review and approval.

Questions

We have attached a copy of the 10-24-2007 E-Mail from the reviewer and a copy of the review. If you have questions about this letter, please contact me at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock dandepa gov (by E-Mail).

Daniel B, Peacock

Daniel B. Peacock, Biologist Insecticide-Rodenticide Branch

Registration Division (7504C)

Attachments: 1. June 5, 2007 Review

2. Approved label (July 2004) with discharge times of 7 and 9 seconds

10,203

COUNTER ASSAULT BEAR DETERRENT - 290 Grams

EFFECTIVENESS DATA

A. SPRAY PATTERN STUDY

On August 8, 2003, Pride Johnson (Chemist) conducted a spray pattern study to verify the spray distance and the spray duration (time) over which Counter Assault Bear Deterrent 290 travels. The study was conducted using ten (10) laboratory-formulated samples and sprayed outdoors at ambient temperature (approximately 65 degrees F at 9:00AM) with little to no wind.

SPRAY SAMPLES

Ten (10) samples were prepared under laboratory conditions using OC Lot # 6000579 to formulate at 2% AI (capsaicin and related capsaicinoids) at 290 grams net content. The formula used is stated in the Confidential Statement of Formula.

PROCEDURE

At 30, 32, and 35-foot distance, the product was sprayed onto an outside wall covered with plastic while a stopwatch measured the spray duration. Verification of the spray pattern was made by visual inspection and by tasting the perimeter of the residue to ensure it had the pungent taste of oleoresin capsicum (OC). The can was weighed before and after spraying. Two (2) cans were shaken prior to spraying.

RESULTS

Distance (feet)		Verification of OC	Spray Duration (seconds)	Can (g		
				Before	After	Difference
1.	35	Very Noticeable	9.21	383.6	91.5	292.1
2.	35 (shaken)	Very Pungent	9.16	385.8	96.2	289.6
3.	32	Extremely Pungent	9.32	386.1	95.8	290.3
4.	32 (shaken)	Extremely Pungent	9.08	383.9	92.7	291.2
5.	30	Extremely Pungent	9.26	384.4	93.7	290.7
		Average	9.206			290.78

SUMMARY

The spray distance of 32 plus feet with an average spray duration of 9.21 seconds gave the best results, regardless of whether the product was shaken.

8,103

COUNTER ASSAULT BEAR DETERRENT - 230 Grams

EFFECTIVENESS DATA

A. SPRAY PATTERN STUDY

On August 7, 2003, Pride Johnson (Chemist) conducted a spray pattern study to verify the spray distance and the spray duration (time) over which Counter Assault Bear Deterrent – 230grams travels. The study was conducted using ten (10) laboratory-formulated samples and sprayed outdoors at ambient temperature (approximately 70 degrees F at 9:45AM) with little to no wind.

SPRAY SAMPLES

Ten (10) samples were prepared under laboratory conditions using OC Lot # 6000579 to formulate at 2% AI (capsaicin and related capsaicinoids) at 230 grams net content. The formula used is stated in the Confidential Statement of Formula.

PROCEDURE

At 25, 30, and 35-foot distance, the product was sprayed onto an outside wall covered with plastic while a stopwatch measured the spray duration. Verification of the spray pattern was made by visual inspection and by tasting the perimeter of the residue to ensure it had the pungent taste of oleoresin capsicum (OC). The can was weighed before and after spraying. Two (2) cans were shaken prior to spraying.

RESULTS

Distance (feet)		Verification of OC	Spray Duration (seconds)	Can (g		
				Before	After	Difference
1.	35	Very Noticeable	7.18	313.5	83.4	230.1
2.	30 (shaken)	Extremely Pungent	6.96	313.2	83.5	229.7
3.	30	Extremely Pungent	7.33	313.1	83.2	229.9
4.	25 (shaken)	Extremely Pungent	7.26	313.8	83.6	230.2
5.	25	Extremely Pungent	7.38	313.9	83.3	230.6
		Average	7.222			230.1

SUMMARY - The spray distance of 30 plus feet with an average spray duration of 7.22 seconds gave the best results, regardless of whether the product was shaken.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF PREVENTION PESTICIOES AND TOXIC SUBSTANCES

July 8, 2004

Counter Assault 120 Industry Court Kalispell, MT 59901

Attention: Mr. Pride Johnson

Subject: Counter Assault Bear Deterrent

EPA Reg. No. 55541-2

Your amended application of November 24, 2004

Your letter of April 29, 2004

Our letters of March 15 and 24, 2004

Purpose The purpose of your submission is to increase the amount of active ingredient to

2%, to change sources of active, and to add a 10.2 oz can size to the existing 8.1 oz

size.

Data review We reviewed the chemistry, acute toxicity, and efficacy (spray pattern test) and found them

to be acceptable. We found the new formula to be no more irritating to the eye (Cat 2) but

more irritating to skin (Cat 3 rather than Cat 4).

Label review These labeling comments reflect our review of your latest data, comments made in our two

March 2004 letters and a review of labeling submitted November 24, 2003, and April 29,

2004.

The labeling for this product [can labels (8.1 oz and 10.2 oz sizes), clamshell insert, and two holster cards], under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is acceptable, provided you submit one (1) copy of final printed labeling to us, with the following changes, before you ship your product.

A. Can Label (8.1 oz and 10.2 oz), November 24, 2003 Version No longer valid;

- 1. Change text in Ingredient Statement under the asterisk (*) as follows:
 - *Includes 1.0% Capsaicin and 1.0% related capsaicinoids
- For the 8.1 oz can, under "USE RESTRICTIONS", change "7.2 seconds" to "7 seconds".

Page 2 of 3

Label reviewcontinued

- For the 10.2 oz can, under "USE RESTRICTIONS", change "9.2 seconds" to "9 seconds".
- Use the preferred presentation of the subheadings "To Arm and Apply" and "To Disarm", as in your April 29, 2004, final printed can label.
- 5. Use Enclosure 1 to revise your "First Aid" text.
- 6. Use Endosure 2 to revise your "Storage and Disposal" text.

B. Clamshell Labeling

There are no comments.

C. Two Holster Cards

There are no comments.

Existing

Stocks of product with existing labels may be used for eighteen (18) months.

Consequence for noncompliance

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Questions

If you have questions about this letter, please contact me at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock.dan@epa.gov (by E-Mail).

Sincerely yours,

Daniel B. Peacock, Biologist Insecticide-Rodenticide Branch

Daniel B. Peacock

Registration Division (7504C)

Page 3 of 3

Enclosure 1. First Aid Text for EPA Reg. No. 55541-2.

Have la	FIRST AID bel with you when obtaining treatment advice, including 1-800-858-7378.
If in eyes	•Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. •Call a poison control center, or doctor, immediately for treatment advice.
If on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center, or doctor immediately for treatment advice.

Enclosure 2. Storage and Disposal Text for EPA Reg. No. 55541-2.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place inaccessible to children and pets. Do not store in places where the temperature is above 120F nor below 32F.

DISPOSAL: Do Not Puncture or Incinerate! If empty: Press valve to release all pressure. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

DIRECTIONS FOR USE: (continued from previous panel)

TO DISARM

Replace safety clip by parting tirmly with thumb and andible "smap" is heard (flo 3) Check to see it safety is completely in place. Ho gap should be vielble between adjustor handle and safety clip.



PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals DANGER:

May cause interestible eye damage if sprayed in the eye at close range. Contact through Louching or rubbing eyes may result in substantial but lempreary eye injury. Strongly initiating to nose and skin. Do not get in eyes, on side, or on clothing. Wash thoroughly with some and water after handling. Remove contaminated clothing and wash clothing before reuse.

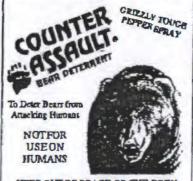
FIRST AID:

IF IN FYES: Hold eye open and rings slowly and pently with water for 15-20 minutes. Remove contact leaves after the first 5 minutes, then continue ringing eye. Call poison control center or doctor for treatment advice. Have product container with you when calling or going for freatment. For emergency medical treatment information call 1-800-535-5053.

PHYSICAL OR CHEMICAL HAZARDS: Extremely flammable. Contents under pressure. Keep sway from fire, aparks and heated surfaces. Do not puncture or incluentle container. Exposore to Imperatores above 130 T may cause bursting.

STORAGE & DISPOSAL STORAGE: STORE IN A COOL DRY PLACE INADCESSIBLE TO CHILDREN. Do not store in places where the imperature is above 120 f nor below 32°E.

DISPOSAL: DO NOT PUNCTURE OR INCINERATE! if emety: Press valve to release all pressure then phase in trach. It purity filled: Call your local solid waste agency of 1-800-CLEANUP for Gsposs) irest nuctions.



KEEP OUT OF REACH OF CHILDREN DANGER

DO NOT EREK OUT ENCOUNTERS WITH BEARS. THIS FROOTICT IS A BEAR ATTACK DETERRENT WHICH MAY PROTECT USERS IN SOME WESTACTED CENTRONTATIONS WITE BRANS BUT MAY NOT BE EFFECTIVE IN ALL SITUATIONS OF PREVENTALL DIVERES. READ THIS ENTIRE LABRE REPORT TAKING THE PRODUCT INTO AREAS WHERE BEARS MIGHT BE ENCOUNTERED. SEE SIDE PANELS FOR PLRET ALD AND PRECAUTIONARY STATEMENTS.

Active Ingredient: Capaldo une related caparidookle* 2.00% 98.00元 Other Ingredient TUTAL 100.00%

"Includes J.A.M.R. Coperiods and G.M.S. related coperiod orbits. Durived from Oleeresia of Capaloum.

Manufactured by: Bushwarker Backguckand Supply Co., Inc. @COUNTERASSAULT 120 Technitrial Court, Kalispell, MT 59901 1-BID-695-3394 + (406) 257-4740 CHEMICAL EMERGENCY: 1-800-535-505

NET CONTENTS: 8.1 ounces (230g)

EPA Reningrado #55541-2 EPA En No.051541-MT-001

DIRECTIONS FOR USE: il is a violation of Federal law to use this product in marrier knoonwistent with its labeling.

USE RESTRICTIONS: This product may be used only to deler been which are affecting or speed likely to ettech breamt. Do not apray this product on objects. tents, or humans; such use has no deterrant effect on bears. Do not seek out encounters will bears or initiationally provide them. Keep safety clip in place except when practicing with or using the groduct. Do not sal or allow to be eaten any food or feed materials which may have become contaminated with this product.

This product has a range of up to 30 feet (8 meters). The center emption in approximately 7.2 records.

APPLICATION DIRECTIONS: Special propedures must be toflowed to som the container, apply the product and restore the safety ofto to disarm the container. Before taking this product into bear country, read the directions below and familiarine yourself with these procedures. If you test-fire this container, make sure the wind is at your back and depress actuator tab for no more than half a second. Do not lest-fire in area inhabited by bears. If test-ligid, clean nozzie and carr with most and water to remove residen from can. If you have not used this product before, you should obtain a County Assault

these activities quisty and accurately. TO ARM AND APPLY Designed for one-hand operation. Place forefinger through hole in handle with thurst on calety dip and. With thumb, pul eafely dip straight back and off (fig 1). Depress adjutter tab for borst of sorey (No 2). Alm at face and ores of hear.

Depress achigher tob for 1-2 seconde in order in create a bearier of apray batheren you and the bear. Stop to evaluate the impact of wind and other letters and edital your eit: if medled before spraying again.

Befuly City DAVECTIONS FOR USE CONTINUED ON WEST PAINEL 00

dieline - does not print.

DIRECTIONS FOR USE: (continued from previous penel)

TO DISARM

Replace safety cilp by pushing firmfy with thumb until audible 'map,' he heard (fig 3). Check to see if safety is completely in place, to pap should be visible between actusion handle and safety cilp.



PRECAUTIONARY STATEMENTS HEZOITS to Herrans and Competit Animals

DANGER:

May cause irreversible eye damage if sprayed in the eye at close range. Contact through Leuching or rubbing eyes may result to substantial but temporary eye injury. Strongly initiating to nose and skin. Do not get in eyes, on side, or on clothing. West thoroughly with soap and water after handling. Remove contambrated clothing and wash clothing before rouse.

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact innexes etter the first 5 mirutes, then continue insing eye. Call poison control center or doctor for treatment advice. Have product container with you when calling or going for treatment. For emergency medical treatment information call 1-800-535-5053.

PHYSICAL OR CHEMICAL HAZARDS:

Extremely flammable. Contents under pressure. Keep away from fire, sparks end heated surfaces. Do not puncture or incherate container. Exposure to temperatures above 190°F may cause bursting.

STORAGE & OFSPOSAL

STORAGE: STORE IN A COOL DAY PLACE INADCESSTRILE TO CHILDREN. Do not store in places where the temperature is above 120 °F nor being 32°F.

DISPOSAL: DO NOT PUNCTURE OR INCINERATE! ill engity: Press valveto release all pressure then place in trash. It partly filled: Call your local solid wants: agency or 1-800-CLEARUP for disposal instructions.



DANGER

DO NOT SEER OUT ENCOUNTERS WITH BEARS. THIS PRODUCT IR A BEAR ATTACK DETERRENT WHICH MAY PROTECT USERS IN BOME UNEXPECTED CONFRONTATIONS WITH BEARS BUT MAY NOT BE EFFECTIVE IN ALL SITUATIONS OR PREVENT ALL RUBLES. READ THIS ENTURE LARRE BEARS MIGHT BE ENCOUNTERED. SEE SIDE PARKES FOR FIRST AID AND PRECAUTIONARY STATEMENTS.

Active Ingredient:

Capsaicin and related capsaicinoids*
Other Legredienis

TOTAL

2.00% 91.00% 100.00%

Machada 1,81% Capanicia and LNS related capanicianita

Derived from Olescale of Cambridge

Manuf scraved by: Buth-weeter Beetpreck and Supply Co., Inc., the COUNTER ASSALLT 120 Industrial Court, Kalispell, MT 59504

1-800-695-3364 • (406) 257-4740 CHEMI CALEMERGENCY: 1-800-533-5013

NET CONTENTS: 10.2 ounces (290g)

EPARgineiro MISAI-2

EN EN ME OSSAL-ATOR

DIRECTIONS FOR USE:

It is a violation of Forder's law to use this product in a counter framelistant with its felbeling.

URE RESTRICTIONE: This product may be used only to date bears which are observed on suppose they to date bears. Which are observed on the product on objects, lenks, or humans; such use has no determent offset on bears. Do not seek out encounters with bears or leasing only up in place size of when practicing with or caing the product. Do not are or allow to be sales any doof or feed materials which may have become contempated with this product.

This product has a raise of up to 22 feet 18 meters). The comister exect so in approximately 9.2 recents.

APPLICATION DIRECTIONS: Special procedures must be followed to arm the container, apply the product and restors the satisty clip to discarm the container. Before taking this product into bear country, read the directions before and timelibrate yourself with these procedures. If you test-fire this container, make sure the wind is at your back and depress act cutor tab for no more than held a second. On met test-fire in area inhabited by bears. If test-fired, clean nazzle and can with soap and water to remove medicule from can. If you have not used this product before, you should obtain a Counter Assault traiving can and graction with it until you can perform these additions quildly and accurately.

TO ARM AND APPLY

Designed for one-hand opwation. Place for finger through hole in bandle with thumb on safety city cust. With thumb, pull safety city straight back and off (fig 1).

and off (fig 1).

Depress actualor tab for burst of spary (fig 2), Alm at face and syes of bear.

Outpress actuator tab by 1-2 seconds in order to create a barrier of spray butween you had the bras. Stop to evaluate the impoct of wind and either lands and eithe

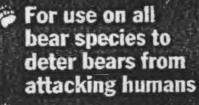




before aproyang again. Sovery Clip
Directions for use constitues are next panel. —

dieline - does not print.

B. Clamshell Labeling, plof 2



Needs no shaking



Glow in the dark safety wedge



Sprays
to 30
feet; 7
seconds
of spray
time



C. Two (2) Holster Cards

3-in-1 Bear Pepper Spray Chest Holster

Charling that was

Chest Holster Belt Holster Swivel Clip

See back of this card for instructions

Chest Hamess

Designed for quick draw our always ready chest hoister is fully adjustable to fit wearer up to 50 inches.

Belt Holster

Easily attaches to belt for convenient access.

Swivel Clip

Heavy duty, metal swivel clip can easily attach to backpacks, saddles and other equipment.

Bear Pepper Spray Belt Holster

Easily attaches to belt for convenient access ----Original Message----

From: Peacock.Dan@epamail.epa.gov [mailto:Peacock.Dan@epamail.epa.gov]

Sent: Tuesday, November 23, 2004 3:45 PM

To: Elizabeth Brown

Subject: Re: Counter Assault 55541-2

Elizabeth,

Subject: Breakout of Capsaicinoids

I overlooked our discussion of this topic. Counter Assault can drop the break out of the capsaicinoids. This was my oversight.

Thank You,

Daniel B. Peacock, Biologist Insecticide-Rodenticide Branch Registration Division (7504C) 1200 Pennsylvania Ave. NW Washington, DC 20460

Tel: 703-305-5407 Fax: 703-305-6596

E-Mail: peacock.dan@epa.gov

Elizabeth Brown brown@chemreg.com>
To Dan Peacock/DC/USEPA/US@EPA
11/23/2004 09:46

Subject: Counter Assault 55541-2

Dan:

Thanks very much for completing the review of the recent amendment in such a timely fashion. Counter Assault appreciates your efforts on that, which has helped them greatly in state renewals due by November 30.

I would like to ask for clarification on one of the comments in the Agency acceptance letter, in order to provide clarification to the registrant and to make certain that I understand:

In Labeling comment A, you required that the footnote be added back in under the Ingredients statement, to show the proportion capsaicin and proportion apsaicinoids. On September 10, we discussed eliminating the footnote completely; that footnote does not appear on competitive products and does not appear to be required by any Agency guidance that I could find. You verbally agreed but identified it needed to be submitted as an amendment. I confirmed our discussion in an email on September 10 and reiterated it in the cover letter submitted with the amendment on September 23. Could you please let me know why the footnote needed to be reinstated for Counter Assault and whether > this is going to be consistent across similar products?

I'd be glad just to discuss this with you, at your convenience. But I wanted to send the question by email, so you had a chance to look back at the correspondence.

Thanks, and I hope you have/had a good Thanksgiving. Please just give me a call when you get a chance.
Regards,
Elizabeth

Elizabeth Anne Brown, Ph.D. Director, Scientific & Regulatory Affairs ChemReg International 1990 Old Bridge Road, Suite 201 Lake Ridge, VA 22192

Phone: 703-492-7905 Fax: 703-492-0668

Email: brown@chemreg.com



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

March 30, 2009

Mr. Pride Johnson, Registered Agent Bushwacker BackPack & Supply Company 120 Industrial Court Kalispell, MT 59901 CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dear Mr. Johnson:

This letter constitutes approval of the attached chart for use on your website. The approved advertising may be used in whole or in part in any advertising medium, provided that when used in part, it is presented in a manner that is not false or misleading.

The Office of Pesticide Programs understands that you also wish to have this chart approved for use in labeling. In order to facilitate review of the chart as labeling, please submit an Amendment to Registration (Form 8570-1) with complete draft labeling.

In the future, if Bushwacker BackPack & Supply Company (Bushwacker) chooses to alter or add claims to advertising beyond those approved in this letter, EPA recommends that Bushwacker seek approval before posting, inasmuch as section 3(c)(1)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires a "statement of all claims" made for a pesticide to be submitted with an application for registration. Future inquiries about additional claims can be submitted to John Hebert.

Sincerely.

JOHN HEBERT

Insecticide-Rodenticide Branch Registration Division (7504P)

Enclosure

cc: Damien M. Schiff, Pacific Legal Foundation David Gunter, DOJ, Erin S. Koch, OGC Daniel Peacock, OPP, Meredith Laws, OPP Jasmine LeDesma, R8, Eduardo Quintana, R8

CARRY WHAT THE PROFESSIONALS CARRY! COUNTER ASSAULT BEAR DETERRENT

Recipient of 1998 Interagency Grizzly Bear Committee* (IGBC) Stewardship Award for Research and Development of Bear Pepper Spray

COMPARISON CHART OF BEAR PEPPER SPRAY

All products in this comparison chart have met EPA requirements and are registered by EPA

Revised October 2008

All products in this comparis				LIDAD		Cognitive Equipment		
Current Regis	Counter Assault		McNeil River Enterprises	UDAP		Security Equipment		
Date EPA Regis	May 12, 1998 (The First) Counter Assault		Dec 22, 1998 Contract Filler	March 18, 1999 Contract Filler		July 17, 2000 Security Equipment		
Manufactured by								
Recommendations of the specialists of the	nd wildlife		Assault	Guard Alaska	Peppe	r Power	Fronti	ersman
Minimum Net Weight	7.9 oz 225 gr	8.1 oz 230 gram	10.2oz 290 gram	9 oz 255 gr	7.9 oz 225 gr	9.2 oz 260 gr	7.9 oz 225 gr	9.2 oz 260 gr
% Capsaicin &		2%	2%					
Related Capsaicinoids	1% - 2%	Produced with OC rated at 3.6 Million SHU's		1.3%	2%	2%	2%	2%
Shotgun-cloud Spray Pattern		Yes	Yes	Yes	Yes	Yes	Yes	Yes
Minimum Spray Distance (Why?)	25 ft	30 ft	30 ft	15-20 ft Does NOT meet IGBC Recommendations	30 ft	30 ft	30 ft	35 ft
Minimum Spray				9 sec	4 sec	5.4 sec	5 sec	5 sec
Time 6 sec (Why?)		7.2 sec 9.2 sec			Does NOT meet IGBC Recommendations		Does NOT meet IGBC Recommendations	
Meets All IGI Recommendat	Counter Assault Meets all IGBC Recommendations!		NO	NO		NO		

Net Weight, % Capsaicin and other Capsaicinoids, Spray Distance and Spray Time as provided below, are taken directly from each product's EPA approved label

*IGBC: The Interagency Grizzly Bear Committee consists of representatives from the U.S. Forest Service, the National Park Service, the U.S. Fish and Wildlife Service, the Bureau of Land Management, the U.S. Geological Survey and representatives of the state wildlife agencies of Idaho, Montana, Washington and Wyoming. In the interest of international coordination and cooperation, the Canadian Wildlife Service is also represented.

Click here for Interagency Grizzly Bear Committee Position Paper (link)

Click here for a list of EPA approved Bear Sprays. (Region 8 Web Site Link)

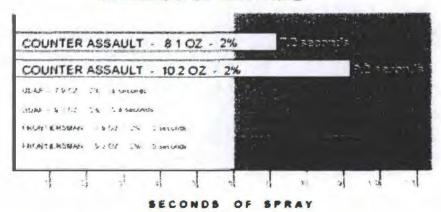
The EPA requires the concentration of Active Ingredient (capsaicin and related capsaicinoids) range between 1% and 2%. The minimum size can the EPA requires is 7.9 ounces or 225 grams. The EPA requires each registrant to provide spray distance and time of continuous spray for their product and include the information on the label, although the EPA has no established limits.

"On the evening of July 25, 2008 at about 7 pm, I took my 13 year old dog for a walk down to the river. We do this walk frequently and always make a lot of noise, this night was no exception. But on our way back we met a brown bear with 2 cubs (don't know how she didn't hear me...). She charged my dog, then promptly turned to me and I was able to unload most of my Counter Assault Bear Deterrent directly In her face. It was like she hit a wall and

there are still skid marks on the dirt road where she came to a halt about 3 feet from me. She then turned around and ran and fortunately I never saw her again." Susy Grimes, Soldotna, Alaska

"Common sense suggests that more range and longer evacuation time would be helpful to someone involved in an encounter with a bear. In my personal experience with bear encounters over the past 20 years, I have found this to be true. Counter Assault Bear Deterrent's extended spray time has saved my life in two separate bear encounters." Tim Rubbert, Wildlife Photographer and Author of Hiking with Grizzlies; Lessons Learned, Whitefish, Montana

MAXIMUM SPRAY TIME



The above chart reflects only bear pepper sprays that meet the minimum distance recommendation as suggested by bear biologists and wildlife specialists of the IGBC*.

COUNTER ASSAULT Meets or exceeds all IBGC* Recommendations!

Why is a Minimum of 25 Feet Important?

- Bears can charge at speeds up to 30+ mph. They need sufficient time to change from a contact charge to a bluff charge.
- If a bear is going to charge more than once, it creates a barrier zone for the bear to have to reenter.
- CROSS Wind may reduce the distance. If a can is capable of spraying 25 feet, it may be reduced to 15
 or 18 feet, but a can that only sprays 18 feet may be reduced to 8 or 9 feet of coverage.

There are many types of ways that bears confront people. The three most common encounter scenarios where the suggested 25 foot spray range will be most beneficial are:

- A sudden dose encounter and defensive charge from 15-25 feet.
- A full defensive charge from more than 50 feet away.
- A gradual continuous approach (curious, predatory or defensive to determine what and who you are).

Why is a Minimum Spray Time of 6 Seconds Important?

- If there is more than one bear, such as mother bear with mature cubs, each one may be charging from different directions.
- More than one bear at a fresh kill site.
- Wind, rain and cold weather.
- More than one charge from a bear.
- More than one encounter.
- Reserve for hiking out.



United States

Environmental Protection Agency Washington, DC 20460

☐ Registration
X Amendment
□ Other

OPP Identifier Number

AMEND

		Application for Pe	esticide - Section I			
1. Company/Product Number 55541-2			Linda Hollis, Branch Chief.		3. Proposed	Classification
4. Company/Product (Name) Bushwacker Backpack and Supply Company, DBA Counter Assault /Counter Assault Bear Deterrent			РМ Biopesticides a Pollution Prevention Division (BPPD)			
5. Name and Address of Applicant (Include ZIP Code) Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904 Check if this is a new address			6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No Product Name			
		Sect	ion - II			
X Amendment - Explain below □ Resubmission in response to Agency le □ Notification - Explain below.	Iter dated		☐ Final printed labels in resp ☐ "Me Too" Application. ☐ Other - explain below.	ponse to Agen	cy letter dated	
Explanation: Use additional page(s) if ne Application for minor label a						
Application for million labera	mendmen	t, IIO FRIA IEE				
		Secti	on - III			
1. Material this Product will be Packag	ed In:					
Child-Resistant Packaging ☐ Yes* ☐ No ☐ No		ing	Water Soluble Packaging ☐ Yes ☐ No		Type of Container	
* Certification must be submitted.	If "Yes," Unit Package	e wgt. No. per container	If "Yes," Unit Package wgt. No. per container		☐ Paper ☐ Other (Specify)	
Location of Net Contents Information Label		4. Size(s) of Retail Contain	iner 5. Location of Label Direction ☐ On Label ☐ On Labeling accompan			
6. Manner In Which Label Is Affixed to Pro	oduct	□ Lithograph □ Paper glued □ Stenciled	Other			
		Secti	on - IV			
Contact Point (Complete items directly items)	below for identil	fication of individual to be cont	tacted, if necessary, to process	this applicatio	n.)	
Name Cristina Griffin			Title Agent for Counter Assault		Telephone No. (Include Area Code) 301-680-7971	
I certify that the statements I have made of knowingly false or misleading statemen	on this form and t may be punish	Certific all attachments thereto are triable by fine or imprisonment	ue, accurate and complete. 1 a	cknowledge th	at any kind	6. Date Application Received
2. Signature Settling Set			3. Title Agent for Counter Assault		(Stamped)	
4. Typed Name Cristina Griffin			5. Date June 21, 2012			

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 8, 2012

Counter Assault c/o Cristina Griffin Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904

Subject:

Reassignment of Pesticide Products from the Registration Division to the

Biopesticides and Pollution Prevention Division

Dear Ms. Griffin:

This letter is to inform you the following product has been reassigned to the Biopesticides and Pollution Prevention Division:

Counter Assault Bear Deterrent, EPA Reg. No. 55541-2

You may address future submissions to the Biochemical Pesticides Branch, Team 91. Please also be aware that any submission under PRIA will now be subject to the Biopesticides and Pollution Prevention Division fee schedule. Further inquiries regarding these products may be directed to Ms. Linda Hollis, chief of the Biochemical Pesticides Branch. Ms. Hollis can be reached by phone at (703) 308-8733, or by email at Hollis.Linda@epa.gov.

Meuslite of Jaws

Meredith Laws, Chief

Insecticide-Rodenticide Branch Registration Division (7505P)

Office of Pesticide Programs

Material Sent for Data Extraction

Reg. #
Description: New letter + label
Material(s) Sent to Data Extraction Contractors:
New Stamped Label Dated _ 8-2-1/
Notification Dated
New CSF(s) Dated
☐ Other:
Decision #: 452538
Other Action/Comments:
File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring down to the (ISC). For further information please call 703-605-0716. Reviewer: Phone: 347-0235 Division: Second Division: S



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL, SAFETY AND POLLUTION PREVENTION

AUG 0 2 2011

Cristina Griffin c/o
Delta Analytical Corp.
12510 Prosperity Drive, Suite 160
Silver Spring, MD 20904

Subject:

Amendment in response to agency letter

EPA Registration No. 55541-2

Primary Brand Name: Counter Assault Bear Deterrent

Submission Date: March 24, 2011

Dear Ms. Griffin:

The labeling referred to above, submitted under FIFRA, as amended, is <u>acceptable</u>. Please submit one (1) final printed copy for the above mentioned label before releasing the product for shipment. If you have any questions, please contact Gene Benbow at (703) 347-0235 or via email at benbow.gene@epa.gov.

Sincerely,

John Hebert

Product Manager 07

Insecticide-Rodenticide Branch Registration Division (7505P)

belint

May cause irreversible eye damage if sprayed in the eye at close range. Contact through touching or rubbing eyes may result; in substantial but temporary eye injury. Strongly irritating to nose and skin. Do not get in eyes, and skin, or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID:

FIN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing eye. Call poison control center or doctor for treatment advice. Have product container with you when calling or going for treatment. For emergency medical treatment information call 1-800-535-5053.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor immediately for treatment advice.

PHYSICAL OR CHEMICAL HAZARDS:

Extremely flammable. Contents under pressure. Keep away from fire, sparks and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

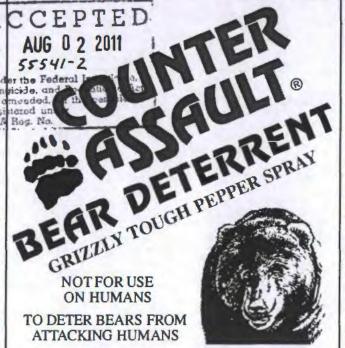
STORAGE & DISPOSAL

STORAGE: STDRE IN A COOL DRY PLACE INACCESSIBLE TO CHILDREN AND PETS. Do not store in places where the temperature is above 120°F nor below 32°F. Do not store in hot vehicle or in direct sunlight.

DISPOSAL: DO NOT PUNCTURE OR INCINERATE!
Non-Refillable Container, Do not reuse of refill this container.

If empty: Press valve to release all pressure then place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions.

Disclaimer: To the extent allowable by law, Counter Assault shall not be liable for damage, injury, loss, direct or consequential including death arising out of the use of, or inability to use this product.



KEEPOUT OF REACH OF CHILDREN DANGER

DO NOT SEEK OUT ENCOUNTERS WITH BEARS. THIS PRODUCT IS A BEAR ATTACK DETERRENT WHICH MAY PROTECT USERS IN SOME UNEXPECTED CONFRONTATIONS WITH BEARS BUT MAY NOT BE EFFECTIVE IN ALL SITUATIONS OR PREVENT ALL INJURIES. READ THIS ENTIRE LABEL BEFORE TAKING THIS PRODUCT INTO AREAS WHERE BEARS MIGHT BE ENCOUNTERED. SEE SIDE PANELS FOR FIRST AID AND PRECAUTIONARY STATEMENTS.

Active Ingredient:

Capsaicin and related capsaicinoids* 2.0 % Other Ingredients 98.0 %

TOTAL

*Derived from Oleoresin of Capsicum

Manufactured by:

Bushwacker Backpack and Supply Co., Inc.

dba COUNTER ASSAULT

120 Industrial Court, Kalispell, MT 59901

1-800-695-3394 (406) 257-4740

• • 1-800-695-3394 • (406) 257-4740 CHEMICAL EMERGENCY: 1-800-535-5053

NET CONTENTS: 8.1 ounces (230g)

EPA Registration #55541-2

EPA Est No: 055541-MT-001

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used only to deter bears which are attacking or appear likely to attack humans. Do not spray this product on objects, tents, or humans; such use has no deterrent effect on bears. Do not seek out encounters with bears or intentionally provoke them. Keep safety clip in place except when practicing with or using the product. Do not eat or allow to be eaten any food or feed materials which may have become contaminated with this product.

This product has a range of up to 30 feet (9 meters). The canister empties in approximately 7 seconds.

APPLICATION DIRECTIONS: Special procedures must be followed to arm the container, apply the product and restore the safety clip to disarm the container. Before taking this product into bear country, read the directions below and familiarize yourself with these procedures. If you test-fire this container, make sure the wind is at your back and depress actuator tab for no more than half a second. Do not test-fire in area inhabited by bears. If test-fired, clean nozzle and can with soap and water to remove residue from can. If you have not used this product before, you should obtain a Counter Assault training can and practice with it until you can perform these activities quickly and accurately.

To Arm and Apply

Designed for one-hand operation. Place forefinger through hole in handle with thumb on safety clip curl. With thumb, pull safety clip straight back and oft (fig 1).

Depress actuator tab for burst of spray (fig 2). Aim at face and eyes of bear. Depress actuator tab for 1-2 seconds in order to create a barrier of spray between you and the bear. Stop to evaluate the impact of wind and other factors and adjust your aim if needed before spraying again.

To Disarm

Replace safety clip by pussing firmly teath thumb until audible "snap" is heard (fig 3). Check to see if safety is completely in place. No gap should be visible betweene, actuator handle and safety cliplenticide Actuator handle and safety cliplenticide Actuator handle and safety cliplenticide.

amended, for the pesucide Registered under

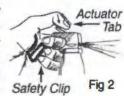


Fig 1



Canister label





Produced by a Grizzly Bear Encounter Survivor

In the early 1980's, bear biologists were researching effective bear deterrents. The result of this research was the development of an atomized spray and led to the creation of Counter Assault.

Pride Johnson, President & Chemist of Counter Assault successfully survived a grizzly encounter with Counter Assault Bear Deterrent. The encounter was immediately stopped.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used only to deter bears which are attacking or appear tikely to attack humans. Do not apray this product on objects, tents, or humans; such use has no deterrent effect on bears. Do not seek out encounters with bears or intentionally provoke them. Keep safety clip in place except when practicing with or using the product. Do not eat or allow to be eaten any food or feed materials which may have become contaminated with this product.

This product has a range of up to 30 feet (9 meters). The canister empties in approximately 7 seconds.

APPLICATION DIRECTIONS: Special procedures must be followed to arm the container, apply the product and restore the safety clip to disarm the container. Before taking this product into bear country, read the directions below and familiarize yourself with these procedures. If you test-fire this container, make sure the wind is at your beck and depress actuator tab for no more than half a second. Do not test-fire in area inhabited by bears. If test fired, clean nozzle and can with soap and water to remove residue from can. If you have not used this product before, you should obtain a Counter Assault training can and practice with it until you can perform the activities quickly and accurately.

TO ARM AND APPLY: Designed for one hand operation. Place forefinger through hole in handle with thumb on safety clip curt. With thumb, pull safety clip straight back and off (fig. 1). Depress actuator tab for burst of spray (fig. 2). Aim at face and eyes of bear. Depress actuator tab for 1.2 seconds in order to create a barrier of apray between you and the bear. Stop to evaluate the impact of wind and other factors and adjust your aim if needed before spraying again.

TO DISARNIt: Replace safety clip by pushing firmly with thumb until audible "snap" is heard (fig 3). Check to see if safety is completely in place. No gap should be visible between actuator handle and safety clip.

PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals

DANGER: May cause irreversible eye damage if sprayed in the eye at close range. Contact through touching or rubbing eyes may result in substantial but temporary eye injury. Strongly initiating to nose and skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID: IF IN EYES: Hold eye open and rinse stowly and gently with water for 15-20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing eye. Call poison control center or doctor for treatment advice. Have product container with you when calling or going for treatment. For emergency medical treatment information call 1 800-535-5053. F ON SKIN OR CLOTHING: Take off contaminated clothing. Pinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor immediately for treatment advice.

PHYSICAL OR CHEMICAL HAZARDS:Extremely flammable. Contents under pressure. Keep away from fire, sparks and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

STORAGE AND DISPOSAL

STORAGE: STORE IN A COOL DRY PLACEINACCESSIBLE TO CHILDREN AND PETS. Do not store in places where the temperature is above 120°F nor below 32°F. Do not store in hot vehicle or in direct sunlight, DISPOSAL: DO NOT PUNCTURE OR INCINERATE! Non-Refillable Container, Do not reuse or refill this container. If empty: Press valve to release all pressure then place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions.

Disclaimer: To the extent allowable by law, Counter Assault shall not be liable for damage, injury, loss, direct or consequential including death arising out of the use of, or inability to use this product.

Reprinted with Permission of Center for Wildlife Information Black Bear Taker Ne shoulder hump Straight face profile Straight face profile

Item# CA12H/sb

NET CONTENTS: 8.1 ounces (230g)

Questions or comments: answers-info@counterassault.com

Manufactured by:
Bushwacker Backpack and Supply Co., Inc.
dba COUNTER ASSAULT
120 Industrial Court, Kalispell, MT 59901
1-800-695-3394 • (406) 257-4740
CHEMICAL EMERGENCY
1-800-535-5053

May cause irreversible eye damage if sprayed in the eye at close range. Contact through touching or rubbing eyes may result in substantial but temporary eye injury. Strongly irritating to nose and skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

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STORAGE & DISPOSAL

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DISPOSAL: DO NOT PUNCTURE OR INCINERATEL Non-Refillable Container. Do not teuse of refill this container.

If empty: Press valve to release all pressure then place in trash or offer for recycling if available. If partly filled: Call your local solid . . . waste agency for disposal instructions.

Disclaimer: To the extent allowable by law-Counter Assault shall not be liable for damage. injury, loss, direct or consequential including death arising out of the use of, or inability to use this product.



KEEPOUT OF REACH OF CHILDREN DANGER

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Active Ingredient:

Capsaicin and related capsaicinoids* 2.0% Other Ingredients

TOTAL

98.0% 100.0%

*Derived from Oleoresin of Capsicum

Manufactured by: Bushwacker Backpack and Supply Co., Inc. dba COUNTER ASSAULT

120 Industrial Court, Kalispell, MT 59901 1-800-695-3394 • (406) 257-4740

CHEMICAL EMERGENCY: 1-800-535-5053

NET CONTENTS: 10.2 ounces (290g)

EPA Registration #55541-2

EPA Est No: 055541-MT-001

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used only to deter bears which are attacking or appear likely to attack humans. Do not spray this product on objects, tents, or humans; such use has no deterrent effect on bears. Do not seek out encounters with bears or intentionally provoke them. Keep safety clip in place except when practicing with or using the product. Do not eat or allow to be eaten with food or feed materials which may have become contaminated with this product.

This product has a range of up to 32 feet (10 meters). The canister empties in approximately 8 seconds.

APPLICATION DIRECTIONS: Special procedures must be followed to arm the container, apply the product and restore the safety clip to disarm the container. Before taking this product into bear country, read the directions below and familiarize yourself with these procedures. If you test-fire this container, make sure the wind is at your back and depress actuator tab for no more than half a second. Do not test-fire in area inhabited by bears. If test-fired, clean nozzle and can with soap and water to remove residue from can. If you have not used this product before, you should obtain a Counter Assault training can and practice with it until you can perform these activities quickly and accurately.

To Arm and Apply

Designed for one-hand operation. Place forefinger through hole in handle with thumb on safety clip curl. With thumb, pull safety clip straight back and off (fig 1).

Depress actuator tab for burst of spray (fig 2). Aim at face and eyes of bear. Depress actuator tab for 1-2 seconds in order to create a barrier of spray between you and the bear. Stop to evaluate the impact of wind and other factors and adjust Safety Clip your aim if needed before spraying again.

To Disarm

Replace safety clip by pushing firmly with thumb until audible "snap" is heard (fig 3). Check to see if safety is completely in place. No gap should be visible between actuator handle and safety clip.

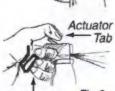
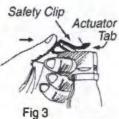


Fig 1





United States

Environmental Protection Agency

☐ Registration

OPP Identifier Number

VEFA			n, DC 20460	X Amen ☐ Other		AMEND
		Application for P	esticide - Section	1		ed.
1. Company/Product Number 55541-2			2. EPA Product Manager John Hebert / Julie Chao		3. Proposed C'assificrtion None Restricted	
4. Company/Product (Name) Bushwacker Backpack and Supply Company, DBA Counter Assault /Counter Assault Bear Deterrent			PM #7			
5. Name and Address of Applicant (Include ZIP Code) Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904 Check If this is a new address			Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name			
		Sect	ion - II			
X Amendment Explain below Resubmission in response to Agency letter dated Notification - Explain below.			☐ Final printed labels in ☐ "Me Too" Application ☐ Other - explain below.	Aon C to Con	ALIG 0 2 2011	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Application for minor label amendment, no PRIA fee				Under the Federal Insecticide, Pungicide, and Rodenticide Act, as amended, for the pesticide Registered under 5554 - 2 EPA Reg. No.		
Section - III			ion - III	DIA neg. 10		
1. Material this Product will be Pac	kaged In:					
Child-Resistant Packaging ☐ Yes* ☐ No	Unit Packag	ing .	Water Soluble Packaging Yes No	9	2. Type of Container D Metal Plastic Glass Paper Other (Specify)	
* Certification must be submitted.	if "Yes," Unit Packag	e wgt. No. per container	If "Yes," Unit Package wgt. N	o. per container		
3. Location of Net Contents Information 4. Size(s) of Retail Conta		ner	5. Location of Label Direction On Label On Labeling accompanying product			
6. Manner in Which Label is Affixed to	Product	☐ Lithograph ☐ Paper glued ☐ Stenciled	☐ Other			
		Sect	ion - IV			
1. Contact Point (Complete items dire	ctly below for Identi	fication of individual to be cor	ntacted, if necessary, to proc	ess this application	on.)	
Name Cristina Griffin			Agent for Counter Assault		Telephone No. (Include Area Code) 301-680-7971	
i certify that the statements I have ma of knowingly false or misleading state			rue, accurate and complete.		nat any kind	6. Date Application Received
2. Signature 2. Si			3. Title Agent for Counter Assault			(Stamped)
4. Typed Name Cristina Griffin			5. Date March 24, 2011			



March 24, 2011

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive, Room S-4900
Arlington VA 22202

Attn: John Hebert, PM 7/Julie Chao, Insecticide-Rodenticide Branch

Re: Application for minor label amendment, no PRIA fee
Product: Counter Assault Bear Deterrent

EPA Reg. No.: 55541-2

Company: Bushwacker Backpack and Supply Company, DBA Counter

Assault

Dear Mr. Hebert:

On behalf of Bushwacker Backpack and Supply Company, DBA Counter Assault, we are submitting a minor label amendment for the product Counter Assault Bear Deterrent, EPA Reg. No. 55541-2. In a letter dated February 11, 2008 (enclosed), EPA approved Counter Assault's CSF submission and spray pattern data with the stipulation that revised labeling incorporating the new formulation's different spray time and distance must be submitted prior to using the new formulation.

The spray time of the new formulation is slightly shorter and the distance is longer. In order to be able to move between formulas as necessary without changing the label each time, Counter Assault has decided to adopt the shorter spray time of the alternate formulation #2 and the shorter distance of the current formulation label. Counter Assault has taken the most conservative approach, and the time/distances were previously approved.

Enclosures:

EPA form 8570-1

Copy of EPA letters dated April 8, 2008 and Feb. 11, 2008

5 copies* of canister label and blister pack card (front and back) for 8.1 ounce product

5 copies* of canister label and blister pack card (front and back) for 10.2 ounce product
 *one color copy, the rest black and white

If you have any questions regarding this submission, please call me a. (301) 680-7971 or email cgriffin@delta-ac.com.

Sincerely.

Cristina Griffin

Agent for Counter Assault

cc: Pride Johnson



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

March 30, 2009

Mr. Pride Johnson, Registered Agent Bushwacker BackPack & Supply Company 120 Industrial Court Kalispell, MT 59901 CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dear Mr. Johnson:

This letter constitutes approval of the attached chart for use on your website. The approved advertising may be used in whole or in part in any advertising medium, provided that when used in part, it is presented in a manner that is not false or misleading.

The Office of Pesticide Programs understands that you also wish to have this chart approved for use in labeling. In order to facilitate review of the chart as labeling, please submit an Amendment to Registration (Form 8570-1) with complete draft labeling.

In the future, if Bushwacker BackPack & Supply Company (Bushwacker) chooses to alter or add claims to advertising beyond those approved in this letter, EPA recommends that Bushwacker seek approval before posting, inasmuch as section 3(c)(1)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires a "statement of all claims" made for a pesticide to be submitted with an application for registration. Future inquiries about additional claims can be submitted to John Hebert.

Sincerely,

JOHN HEBERT

Insecticide-Rodenticide Branch Registration Division (7504P)

Enclosure

cc: Damien M. Schiff, Pacific Legal Foundation David Gunter, DOJ, Erin S. Koch, OGC Daniel Peacock, OPP, Meredith Laws, OPP Jasmine LeDesma, R8, Eduardo Quintana, R8

CARRY WHAT THE PROFESSIONALS CARRY! COUNTER ASSAULT BEAR DETERRENT

Recipient of 1998 Interagency Grizzly Bear Committee* (IGBC) Stewardship Award for Research and Development of Bear Pepper Spray

COMPARISON CHART OF BEAR PEPPER SPRAY

All products in this comparison chart have met EPA requirements and are registered by EPA Revised October 2008 **Current Registrant** UDAP Counter Assault McNeil River Security Equipment **Enterprises** Date EPA Registered Dec 22, 1998 March 18, 1999 May 12, 1998 July 17, 2000 (The First) Manufactured by Counter Assault Contract Filler Contract Filler Security Equipment Recommendations suggested by bear biologists and wildlife Guard Alaska Pepper Power Frontiersman Counter Assault specialists of the IGBC Minimum Net 9.2 oz 7.9 oz 8.1 oz 10.20z 9 oz 7.9 oz 9.2 oz 7.9 oz Weight 225 gr 255 gr 225 gr 260 gr 225 gr 260 gr 230 gram 290 gram % Capsaicin & 2% 1% - 2% Produced with OC rated Related 1.3% 2% 2% 2% 2% Capsaicinoids at 3.6 Million SHU's Shotgun-cloud Spray Pattern Yes Yes Yes Yes Yes Yes Yes Minimum Spray 15-20 ft Does NOT meet IGBC Distance 25 ft 30 ft 30 ft 35 ft 30 ft 30 ft 30 ft Recommendations (Why?) Minimum Spray 9 sec 4 sec 5.4 sec 5 sec 5 sec Time 6 sec 7.2 sec 9.2 sec Does NOT meet IGBC Does NOT meet IGBC (Why?) Recommendations Recommendations Counter Assault Meets Al IGBC* NO NO NO Meets all IGBC Recommendations?

Net Weight, % Capsalcin and other Capsalcinoids, Spray Distance and Spray Time as provided below, are taken directly from each product's EPA approved label

Recommendations!

*IGBC: The Interagency Grizzly Bear Committee consists of representatives from the U.S. Forest Service, the National Park Service, the U.S. Fish and Wildlife Service, the Bureau of Land Management, the U.S. Geological Survey and representatives of the state wildlife agencies of Idaho, Montana, Washington and Wyoming. In the interest of international coordination and cooperation, the Canadian Wildlife Service is also represented.

Click here for Interagency Grizzly Bear Committee Position Pager (link)

Click here for a list of EPA approved Bear Sprays. (Region 8 Web Site Link)

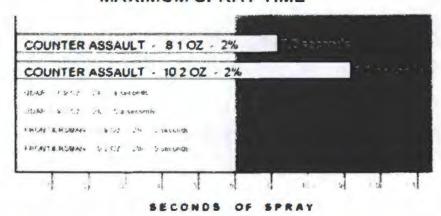
The EPA regulres the concentration of Active Ingredient (capsaicin and related capsaicinoids) range between 1% and 2%. The minimum size can the EPA requires is 7.9 ounces or 225 grams. The EPA requires each registrant to provide spray distance and time of continuous spray for their product and include the information on the label, although the EPA has no established limits.

"On the evening of July 25, 2008 at about 7 pm, I took my 13 year old dog for a walk down to the river. We do this walk frequently and always make a lot of noise, this night was no exception. But on our way back we met a brown bear with 2 cubs (don't know how she didn't hear me...). She charged my dog, then promptly turned to me and I was able to unload most of my Counter Assault Bear Deterrent directly in her face. It was like she hit a wall and

there are still skid marks on the dirt road where she came to a halt about 3 feet from me. She then turned around and ran and fortunately I never saw her again." Susy Grimes, Soldotna, Alaska

"Common sense suggests that more range and longer evacuation time would be helpful to someone involved in an encounter with a bear. In my personal experience with bear encounters over the past 20 years, I have found this to be true. Counter Assault Bear Deterrent's extended spray time has saved my life in two separate bear encounters." Tim Rubbert, Wildlife Photographer and Author of Hiking with Grizzlies: Lessons Learned, Whitefish, Montana

MAXIMUM SPRAY TIME



The above chart reflects only bear pepper sprays that meet the minimum distance recommendation as suggested by bear biologists and wildlife specialists of the IGBC*.

COUNTER ASSAULT Meets or exceeds all IBGC* Recommendations!

Why is a Minimum of 25 Feet Important?

- Bears can charge at speeds up to 30+ mph. They need sufficient time to change from a contact charge to a bluff charge.
- If a bear is going to charge more than once, it creates a barrier zone for the bear to have to reenter.
- CROSS Wind may reduce the distance. If a can is capable of spraying 25 feet, it may be reduced to 15
 or 18 feet, but a can that only sprays 18 feet may be reduced to 8 or 9 feet of coverage.

There are many types of ways that bears confront people. The three most common encounter scenarios where the suggested 25 foot spray range will be most beneficial are:

- A sudden close encounter and defensive charge from 15-25 feet.
- A full defensive charge from more than 50 feet away.
- A gradual continuous approach (curious, predatory or defensive to determine what and who you are).

Why is a Minimum Spray Time of 6 Seconds Important?

- If there is more than one bear, such as mother bear with mature cubs, each one may be charging from different directions.
- . More than one bear at a fresh kill site.
- Wind, rain and cold weather.
- More than one charge from a bear.
- More than one encounter.
- Reserve for hiking out.



120 Industrial Court Kalispell, MT 59901 406-257-4740 Fax: 406-257-6674 email: original@counterassault.com

October 15, 2007

Mr. John Hebert Insecticide-Rodenticide Branch, Registration Branch Office of Pesticide Programs (7505P) US Environmental Protection Agency One Potomac Yard Arlington, VA 22202

RE: Counter Assault Bear Deterrent

EPA Reg. No. 55541-2

Labeling Issues, 9-13-07 Meeting with Dan Peacock & Bill Jacobs

Mr. Hebert,

We believe the FIFRA and CFR guidelines are being applied differently to Counter Assault than they are to our competitors. Based on competitors' approved labels found on the EPA Pesticide Product Label System (PPLS), we expected that there had been a change in EPA interpretation in regards to bear pepper spray. At the September 13, 2007 meeting with Dan Peacock and Bill Jacobs, we learned this was not the case, at least for Counter Assault. Although you were not at this meeting, this letter is addressed to your attention in an effort to correct this inequity.

The attached summary and supporting documents show years of incidences where FIFRA and CFR have been interpreted to disallow Counter Assault's marketing information as "false and misleading" while allowing our competitors to use similar and sometimes exact phrases. This has put us at a severe marketing disadvantage and we believe this inconsistent interpretation has been intentional.

In an EPA letter dated August 11, 1999 (copy attached with supporting documents) page 3 states "...people in the pepper spray industry pay keen attention to the labeling and promotional activities of their competitors. In such an environment, we feel that strict adherence to the requirement of 40 CFR, §156.10 (a) (5) serves the best interests of the public, EPA, and ultimately those of the registrants." It appears to us that Counter Assault is the only one that this opinion seems to apply. We expect equal interpretation of the CFR as provided to our competitors.

By allowing competitors to use certain statements and not allowing Counter Assault to use similar statements it seems the EPA is trying to influence consumers purchasing. In the same letter, Mr. Peacock refers to some Counter Assault requests touching "an especially sensitive nerve with us because of the history of sales of bear pepper sprays as unregistered pesticides." Is there a grudge against Counter Assault? The current

SUMMARY

1. Counter Assault Bear Deterrent disperses large amounts of active ingredients in a sufficient amount of time.

OK

<u>EPA Comments</u>: Mr. Jacobs and Mr. Peacock first indicated they did not understand why we would want to make such a claim. Then they said "sufficient amount of time" was vague and therefore would not be allowed.

<u>Counter Assault Response:</u> We provided a copy of a competitors' stamped supplemental labeling with a very similar phrase. The only difference is the use of the word "short" instead of "sufficient".

72007

UDAP stamped booklet

July 19, 2004

page 13 of 16

According to Webster's Ninth Collegiate Dictionary, the word "short" has many variations of describing "brief duration" as well as "insufficiently supplied" whereas "sufficient" means "enough to meet the needs of a situation or a proposed end". It is our intent to use the best word to properly describe the spray required to deter a bear attack in most situations. A "short amount of time" may be perceived that the smaller personal defense spray is adequate; which it is not.

EPA Response: No Comment.

We request equal interpretation of the CFR as provided to our competitors.

2. Counter Assault Bear Deterrent Works on All Bear Species



<u>EPA Comments</u>: Did not like this choice of the word "works". Counter Assault currently uses the phrase "For use on all bear species". They felt this was a better choice of words.

<u>Counter Assault Response:</u> We provided copies of a competitor's EPA stamped label and supplemental labeling with the statements "Works on All Bear Species" and "From a Hunter to a Hunter <u>UDAP</u> Bear spray works"

UDAP stamped label UDAP stamped booklet March 5, 2007 July 19, 2004 pages 4 & 6 of 9 page 5 of 16

EPA Response: Stated that the word "works" would be taken into consideration.

<u>Counter Assault Comments</u>: In reviewing files we found a reference to the words "proven to work" where Counter Assault requested this in 1999. The EPA responded that ""proven to work" text goes well beyond the actual data base that we considered prior to deciding to accept claims that Counter Assault deters bears." It seems that

Progress Report 1982 Summary describes the test parameters, procedures and protocols that were used to evaluate potential deterrents for bears.

Progress Report 1983 refers to the name "Phaser". Although the report did not mention who provided Phaser; page 19 of the report acknowledges a "B. Pounds".

The 1984 Field Season Update refers to a product called "Animal Repel".

The Final Report, March 1985 actually connects Counter Assault Bear Deterrent with the previous generations of bear deterrents that were tested. The Table of Contents refers to "Animal Repel" (Capsaicin Product) by Bushwacker Backpack and Supply Company (BBSC). Bill Pounds is the original developer and owner of BBSC. Pages 22-27 of the Final Report, March 1985 discusses that "Phaser" was an earlier generation of "Animal Repel". The report indicates on page 23 that "Animal Repel was developed specifically for use on bears by the Montana based Bushwacker Backpack and Supply Company...with an atomized spray ... and a capsaicin solution of 10%".

The Montana Department of Agriculture letter to Dr. Jonkel gives "permission for further experimental use of capsicum spray "Counter Attack" distributed by Bushwacker Backpack and Supply Company".

The University of Montana letter from Dr. Jonkel acknowledges Counter Assault and BBSC.

In conclusion, the generations of products that led to Counter Assault Bear Deterrent were "developed" in conjunction with the University of Montana and the Border Grizzly Project. This testing confirmed that the active ingredients derived from Oleoresin of Capsicum is an effective bear deterrent when delivered in an atomized spray. This testing is the basis for the EPA registration of all bear deterrents containing capsicum.

Counter Assault had presented all the above reports and letters during the original registration process and again through subsequent communications. The only new document is the Montana Department of Agriculture letter.

<u>EPA Response</u>: Mr. Jacobs stated that we had "tied the bow" by explaining the generations of names used in the development of Counter Assault Bear Deterrent. He did not state one way or the other if the phrases would be accepted.

<u>Counter Assault Comments</u>: Mr. Jacobs seemed satisfied with the information provided. Counter Assault Bear Deterrent is undisputedly the first bear pepper spray to be developed, tested, and registered by U.S. EPA. This is simply a true statement and was acknowledged by the EPA in a Press Advisory issued on September 25, 1998.

EPA REGISTERS NEW BEAR REPELLENT PRODUCT September 25, 1998 Email from Dan Peacock dated September 29, 1998 5. Recipient of the Interagency Grizzly Bear Committee's Stewardship Award for research and development of bear pepper spray

and/or

Recipient of the Stewardship Award for Research and Development of bear pepper spray

<u>Background</u>: Counter Assault has requested the addition of the above phrases numerous times in various sentence compositions with basically the same meaning. Although the statements are true because we have the award to prove it, we were denied every time. The Interagency Grizzly Bear Committee (IGBC) awarded its Stewardship Award to Bushwacker Backpack and Supply Company, dba Counter Assault in 1998. The IGBC is comprised of members of the US Forest Service, the National Park Service, the US Fish & Wildlife Services, the Bureau of Land Management, and the State Wildlife Agencies in Montana, Idaho, Wyoming, and Washington. The IGBC's mission is to manage grizzly bears and their habitat in the 4 states mentioned previously.

<u>EPA Comments</u>: We were verbally denied using the same justification as used previously. "A true statement used in such a way as to give a false or misleading impression to the purchaser". Under <u>40 CFR</u>, §156.10 (a) (5) (vii), such statements are categorically considered to be "false and misleading" statements which would misbrand any pesticide product if they appeared on that product's labeling. It also could be argued that some or all of these statements imply favorable comparisons with unnamed competitive products. Such statements are considered under <u>40 CFR</u>, §156.10 (a) (5) (iv), which makes it illegal to make "A false or misleading comparison with other pesticides or devices." They did ask us to provide a picture of the Award and provided us a copy of the appropriate CFR.

EPA letter

August 11, 1999

page 2 of 4

<u>Counter Assault Response</u>: We provided copies of a competitor's EPA stamped label and supplemental labeling where the use of a statement we believe is "A true statement used in such a way as to give a false or misleading impression to the purchaser" or to make "A false or misleading comparison with other pesticides or devices." have been allowed. These copies were obtained from the EPA website PPLS. The stamped label shows a graphic bloody picture of a grizzly attack survivor on the actual canister label. The insert card has the same picture (larger) and a narrative about how UDAP Industries began. The final sentence reads "This bear attack is what motivated Mark to establish UDAP Industries, Inc." We believe this certainly is misleading and could give the impression that UDAP Industries developed bear deterrents.

UDAP stamped label UDAP stamped booklet

March 5, 2007 July 19, 2004 pages 3& 7 of 9 page 16 of 16

EPA letter	October 20, 2000	page 2 of 8
EPA letter	April 16, 2001	page 2 of 3
EPA letter	December 21, 2001	page 3 of 5
EPA letter	August 05, 2002	page 5 of 7

In November 2002, we discovered a competitor was using their website on packaging and notified the EPA in a letter dated November 12, 2002.

Counter Assault letter

November 12, 2002

page 1 of 2

Six months later, we received a response stating that the competitor had "inappropriately referred to a web site" and that "corrective actions have been undertaken".

EPA letter

April 7, 2003

page 1 of 2

<u>EPA Comments</u>: We were verbally denied. They both seemed to very adamant about not allowing our email addresses because it contains our website address. They did not have to ponder the question, but immediately denied our request. Mr. Peacock and Mr. Jacobs informed us that <u>NO</u> websites or email addresses containing website names would be approved for any EPA bear spray label and the EPA was not going to address any electronic material because the material "could easily and frequently be altered".

<u>Counter Assault Response</u>: We provided copies of two competitors' EPA stamped labels and supplemental labeling where the use of email addresses containing the website address have been allowed. These copies were obtained from the EPA website Pesticide Product Label System (PPLS). One instance is the very company the EPA refers to in their letter dated April 7, 2003 (referenced above) as having "inappropriately referred to a web site" and that "corrective actions have been undertaken".

UDAP stamped booklet Frontiersman stamped label July 19, 2004 December 22, 2004 page 1 of 16 pages 1& 4 of 6

<u>EPA Response</u>: Attributed to an oversight. They had not reviewed and approved the content of any websites.

<u>Counter Assault Comments</u>: It is understandable that an oversight might occur, but this issue was brought to Mr. Peacock's attention and he informed me that corrective action had been taken. Within a year of notification, a competitor was approved to use their email address containing the website address and 5 months later another label was approved with the same type email address. It seems unlikely that these were oversights when this issue had been addressed at least five times in EPA correspondence from Mr. Peacock to Counter Assault.

We request equal interpretation of the CFR as provided to our competitors.

<u>Counter Assault Comments</u>: Why not just say yes and move on? We provided documentation that they had already approved the word. In our discussions they seemed very sensitive to any words that might associate bear deterrent with a gun or gun like actions, but they have approved the use of the word "Fires" on a competitors' label. This could have same sort of association. It seems that the EPA is more particular about wording on Counter Assault products perhaps than on our competitors.

Frontiersman stamped label

December 22, 2004

pages 2 & 5 of 6

Counter Assault requests the option to change the word "sprays" on our label and packaging to the word "fires". This was not discussed at the meeting.

We request equal interpretation of the CFR as our competitors.

9. Developer of high emission "atomized" fire extinguisher style pepper spray used in bear deterrents.

<u>Discussion</u>: The final research report by Carrie Hunt, makes the first reference to an "atomized" spray. "Animal Repel was developed specifically for use on bears by the Montana based Bushwacker Backpack & Supply Co.,...with an atomized spray ... and a capsaicin solution of 10%". The EPA requires all registered bear sprays to be an atomized spray.

Final Report, March 1985

Page 23

EPA Comments: Mr. Peacock and Mr. Jacobs did not provide comment.

10. Tough 600 Denier Polyester Holster

0-

<u>Discussion</u>: Mr. Peacock and Mr. Jacobs had a difficult time with the word "tough" although the EPA has approved our slogan as "Grizzly Tough Pepper Spray". We did not agree on a word that adequately described the durability of the holster. The specification sheet for the fabric used in the manufacturing the holster identifies several ASTM methods. This information is provided to gain a better understanding for the quality of the fabric's yarn. The term "denier", in fabric terminology, is a unit of yarn fitness weighing one gram for each 9000 meters; 100-denier yarn is finer than 150-denier yarn.

Specification Sheet for 600 Denier Polyester

<u>EPA Comments</u>: They would evaluate the information provided and offer an opinion at a later date.





120 Industrial Court Kalispell, MT 59901 406-257-4740 Fax: 406-257-6674

email: original@counterassault.com

55541-2

April 28, 2008

Mr. John Hebert USEPA Headquarters Ariel Rios Building 1200 Pennsylvania Ave NW Mail Code: 7505P Washington, DC 20460

RE: Market Labels and Insert Card for Counter Assault

Mr. Hebert,

Per your instructions, I have enclosed copies of the new printed labels and insert cards for Counter Assault.

Best regards,

Kirsten K Johnson

CFO

Counter Assault

NOT REVIEWED In Accordance with PR Notice 82-2 Based on Dran Labeling Dated

MAR 2 7 2009

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals DANGER:

May cause irreversible eye damage if sprayed in the eye at close range. Contact through touching or rubbing eyes may result in substantial but temporary eye injury. Strongly irritating to nose and skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing eye. Call poison control center or doctor for treatment advice. Have product container with you when calling or going for treatment. For emergency medical treatment information call 1-800-535-5053.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 20 minutes. Call poison control center or doctor immediately for treatment advice.

PHYSICAL OR CHEMICAL HAZARDS:

Extremely flammable. Contents under pressure. Keep away from fire, sparks and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

STORAGE & DISPOSAL STORAGE: STORE IN A COOL DRY PLACE INACCESSIBLE TO CHILDREN AND PETS. Do not store in places where the temperature is above 120°F nor below 32°F. Do not store in hot vehicle or in direct sunlight.

DISPOSAL: DO NOT PUNCTURE OR INCINERATE! Non Refilable Container. Do not reuse or refill this container.

If empty: Press valve to release all pressure then place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions.

Disclaimer: To the extent allowable by law, Counter Assault shall not be liable for damage, injury, loss, direct or consequential including death arising out of the use of, or inability to use this product.



KEEP OUT OF REACH OF CHILDREN DANGER

DO NOT SEEK OUT ENCOUNTERS WITH BEARS. THIS DO NOT SEEK OUT ENCOUNTERS WITH BEARS, THIS PRODUCT IS A BEAR ATTACK DETERRENT WHICH MAY PROTECT USERS IN SOME UNEXPECTED CONFRONTATIONS WITH BEARS BUT MAY NOT BE EFFECTIVE IN ALL SITUATIONS OR PREVENT ALL INJURIES. READ THIS ENTIRE LABEL BEFORE TAKING THIS PRODUCT INTO AREAS WHERE BEARS MIGHT BE ENCOUNTERED, SEE SIDE PANELS FOR FIRST AID AND PRECAUTIONARY STATEMENTS.

Active Ingredient:

Capsa icio and related capsa icinoids* 2.0% Other Ingredients 98.0% 100.0% TOTAL.

*Derived from Oleoresin of Capsicum

Manufactured by: Bushwacker Backpack and Supply Co., Inc. dba COUNTER ASSAULT 120 Industrial Court, Kalispell, MT 59901 1-800-695-3394 + (406) 257-4740 CHEMICAL EMERGENCY: 1-800-535-5053

NET CONTENTS: 10.2 ounces (290g)

EPA Registration #55541-2

EPA En Nov 05554 LMCC.001

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used only to deter bears which are attacking or appear likely to attack humans. Do not spray this product on objects, tents, or humans; such use has no deterrent effect on bears. Do not seek out encounters with bears or intentionally provoke them. Keep safety clip in place except when practicing with or using the product. Do not eat or allow to be eaten any food or feed materials which may have become contaminated with this product.

This product has a range of up to 32 feet (10 meters). The canister empties in approximately 9.2 seconds.

APPLICATION DIRECTIONS: Special procedures must be followed to arm the container, apply the product and restore the safety clip to disarm the container. Before taking this product into bear country, read the directions below and familiarize yourself with these procedures. If you test-fire this container, make sure the wind is at your back and depress actuator tab for no more than half a second. Do not test-fire in area inhabited by bears. If test-fired, clean nozzle and can with soap and water to remove residue from can. If you have not used this product before, you should obtain a Counter Assault training can and practice with it until you can perform these activities quickly and accurately.

To Arm and Apply

Designed for one-hand operation. Place forefinger through hole in handle with thumb on safety clip curt. With thumb, pull safety dip straight back and off (fig 1).

Depress actuator tab for burst of spray (fig 2) Aim at face and eyes of bear. Depress actuator tab for 1-2 seconds in order to create a barrier of spray between you and the bear. Stop to evaluate the impact of wind and other factors and adjust your Safety Clip aim if needed before spraying again.

To Disarm

Replace safety clip by pushing firmly with thumb until audible "snap" is heard (fig 3). Check to see if safety is completely in place. No gap should be visible between actuator handle and safety clip.





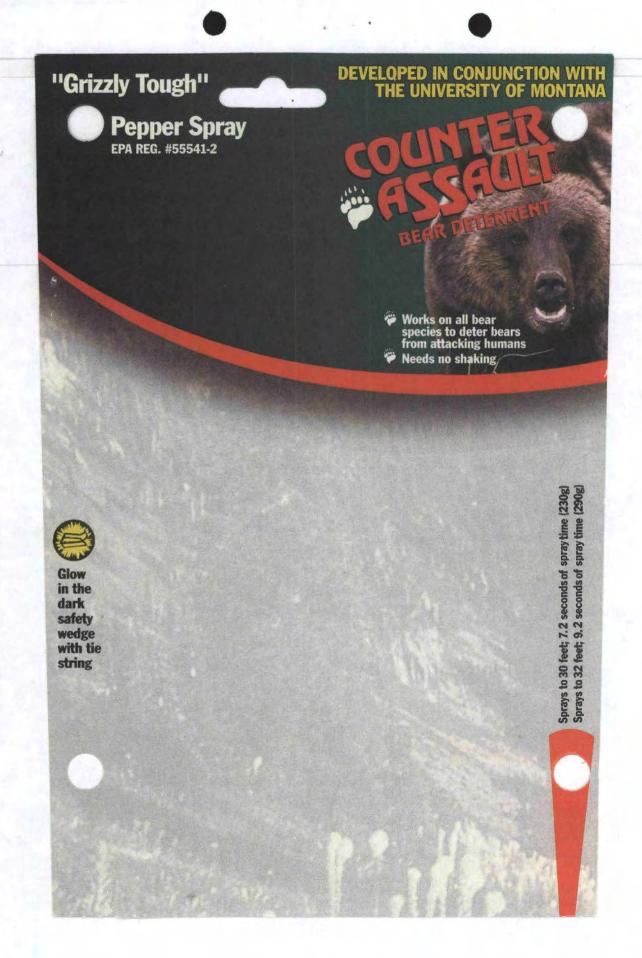


Fig. 2

PRODUCED BY A GRIZZLY ENCOUNTER SURVIVOR!

In the early 1980's, bear biologists were researching effective bear deterrents. The result of this research was the development of an atomized spray and led to the creation of Counter Assault.

Pride Johnson, President & Chemist of Counter Assault successfully survived a grizzly encounter with Counter Assault Bear Deterrent. The encounter was immediately stopped.

COUNTER ASSAULT BEAR DETERRENT PEPPER SPRAY

DETECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its lebeling.

USE RESTRICTIONS: This product may be used only to deter bears which are attacking or appear likely to attack humans. Do not spray this or product on objects, tents, or humans; such use has no deterrent effect on bears. Do not seek out encounters with bears or intentionally provoke them. Keep safety clip in place except when practicing with or using the product. Do not eat or allow to be eaten any food or feed materials which may have become contaminated with this product.

This product has a range of up to 30 feet (9 meters) (230g canister) and 32 feet (10 meters) (290g canister). The canister empties in approximately 7.2 seconds (230g canister) and 9.2 seconds (230g canister).

APPLICATION DIRECTIONS: Special procedures must be followed to arm the container, apply the product and restore the safety clip to disarm the container. Before taking this product into bear country, read the directions below and familiarize yourself with these procedures. If you test fire this container, make sure the wind is at your back and depress actuator tab for no more than half a second. Do not test fire in area inhabited by bears. If test-fired, clean nozzle and can with soap and water to remove residue from can. If you have not used this product before, you should obtain a Counter Assault training can and practice with it until you can perform the activities quickly and accurately.

TO AITM AND APPLY: Designed for one-hand operation. Place forefinger through hote in handle with thumb on safety clip curl. With thumb, pull safety clip straight back and off (fig 1). Depress actuator tab for burst of spray (fig 2). Aim at face and eyes of bear. Depress actuator tab for 1-2 seconds in order to create a barrier of spray between you and the bear. Stop to evaluate the impact of wind and other factors and adjust your aim if needed before

spraying again.

TO DESARIA: Replace safety clip by pushing firmly with thumbuntil audible "snap" is heard (fig 3). Check to see if safety is completely in place. No gap should be visible between actuator handle and safety clip

PRECAS/TIONARY STATEMENTS: Hazards to Humans and Domestic Animals

DANGER: May cause irreversible eye damage if sprayed in the eye at close range. Contact through touching or rubbing eyes may result in substantial but temporary eye injury. Strongly irritating to nose and skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST ALD:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing eye. Call poison control center or doctor for treatment advice. Have product container with you when calling or going for treatment. For emergency medical treatment information call 1-800 535 5053.

IF ON SIGN OR CLOTHENG: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 20 minutes. Call poison control

center or doctor immediately for treatment advice.

PHYSICAL OR CHEMICAL HAZARDS:

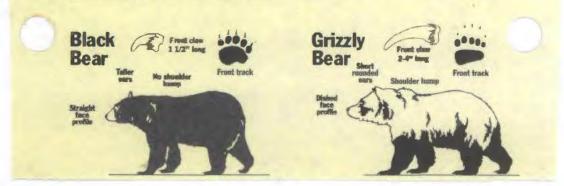
Extremely flammable. Contents under pressure. Keep away from fire, sparks and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

STORAGE: STORE IN A COOL DRY PLACE INACCESSIBLE TO CHILDREN AND PETS. Do not store in places where the temperature is above 120°F nor below 32°F. Do not store in hot vehicle or in direct sunlight.

DISPOSAL: DO NOT PUNCTURE OR INCINERATE! Non-Refillable Container. Do not reuse or refill this container. If empty: Press valve to release all pressure then place in trash or offer for recycling if available. If partity filled: Call your local solid waste agency for disposal instructions.

Disclaimer:

To the extent allowable by law, Counter Assault shall not be liable for damage, injury, loss, direct or consequential including death arising out of the use of, or inability to use this product.



55

Item # CA-12H/cl

Manufactured by: Bushwacker Backpack and Supply Co., Inc. dba COUNTER ASSAULT 120 Industrial Court, Kaispel, MT 59901 1800-695 3394 · (406) 257-4740 CHEMICAL EMERGENCY 1-800-535-5053

NET CONTENTS: 8.1 ounces (230g)

original@counterassault.com

extinguisher style spray used in bear deterrents. (see back of card) Developer of high emission "atomized" fire





Magnum 290
NET CONTENTS:
10.2 ounces (290g)
original@counterassault.com

Manufactured by:
Bushwacker Backpack and Supply Co., Inc.
dba COUNTER ASSAULT
120 Industrial Court, Kalispell, MT 59901
1-800-695-3394 • (406) 257-4740
CHEMICAL EMERGENCY
1-800-535-5053



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES

April 8, 2008

Counter Assault c/o Ms. Cristina Griffin Delta Analytical Corporation 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904

Dear Ms. Griffin:

Subject: Follow-up to Agency correspondence dated 3/21/08 and your letter dated 4/1/08, regarding your request to maintain current label claims until conversion to Alternate CSF #2 has taken effect

Product Name: Counter Assault Bear Deterrent

EPA Registration No.: 55541-2

Your request to maintain the current time/distance spray claims on the labeling for the above referenced product is acceptable. As outlined in your letter of 4/1/08, you must submit to the Agency an amended label incorporating the spray claim labeling changes required by Agency correspondence dated 3/21/08 prior to converting to Alternate Formulation #2. With the exception of the spray claims, all other changes noted in the Agency's letter dated 3/21/08 must be implemented at your next label printing (or once the 18 month period for use of existing stocks has expired).

If you have any questions, please contact Julie Chao at (703) 308-8735 or chao.julie@epa.gov.

John Hebert

Regards,

Insecticide-Rodenticide Branch Registration Division (7505P) Julie Chao/DC/USEPA/US 04/08/2008 02:34 PM

To "Cristina Griffin" <cgriffin@delta-ac.com>

cc John Hebert/DC/USEPA/US@EPA

bcc

Subject Fw: Counter Assault, EPA #55541-2

Hi Cristina,

Attached is a letter acknowledging Counter Assault's request dated April 1, 2008. Because you had come to an earlier agreement with Dan Peacock, we are going to allow you to maintain the current label claims until the conversion to alternate formulation #2 has taken place. Please note, however, that this is not typical and should be considered a one-time courtesy.

Typically, once we approve a formulation, it is considered "active" and goes into the official records. Once approved, we do not distinguish between "active" formulations that are in use and those that are not. At that point, all labeling is reviewed in accordance with the data supporting that formulation.

If you have any further questions about this issue, or questions on how to proceed with future labe/CSF submissions, please do not hesitate to contact me or John Hebert.



Thanks, Julie

703.308.8735 (phone) 703.305.6920 (fax) http://www.epa.gov/pesticides

U.S. Postal Service Mailing Address: U.S. Environmental Protection Agency Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave NW Washington, DC 20460

Courier Deliveries: U.S. Environmental Protection Agency Registration Division, Room S-4900 2777 Crystal Drive, One Potomac Yard Arlington, VA 22202

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— Forwarded by John Hebert/DC/USEPA/US on 04/03/2008 11:47 AM ----



"Cristina Griffin"
<cgriffin@delta-ac.com>
04/03/2008 09:43 AM

To John Hebert/DC/USEPA/US@EPA



Subject FW: Counter Assault, EPA #55541-2

John,

As we discussed, here is the e-mail Dan Peacock asked me to send after my telephone conversation with him. At that time, he agreed not to send a letter requiring Counter Assault to change the time/distance on the label if we would send an e-mail committing to submit a label amendment before converting to the new formula. I also am re-sending the letter drafted a few days ago (which makes the same commitment) so it can be put into the registration jacket.

Thank you for your help. We are assuming that based on this, the current label will be stamped as is. If there are any questions or issues, please call.

Best Regards, Cristina Griffin Delta Analytical Corp. e-mail: cgriffin@delta-ac.com voice: 301-680-7971 fax: 301-680-7975 12510 Prosperity Drive, Suite 160 Silver Spring MD 20904

-----Original Message----From: Cristina Griffin [mailto:cgriffin@delta-ac.com]
Sent: Wednesday, February 20, 2008 10:50 AM
To: 'Peacock.Dan@epamail.epa.gov'
Cc: 'Pride Johnson'
Subject: Counter Assault, EPA #55541-2

Dan,

As we discussed on the telephone a few minutes ago, Counter Assault is not prepared to convert to the new formula immediately, and needs some time to consider how they will proceed. Therefore, we request that no formal action be taken regarding the labeling at this time. We will submit a label amendment to address label changes resulting from the new formula.

Best Regards,
Cristina Griffin, Agent for Counter Assault
Delta Analytical Corp.
e-mail: cgriffin@delta-ac.com
voice: 301-680-7971
fax: 301-680-7975
12510 Prosperity Drive, Suite 160
Silver Spring MD 20904



April 1, 2008

Mr. John Hebert, PM 7, Insecticide-Rodenticide Branch Office of Pesticide Programs (7504C) Environmental Protection Agency One Potomac Yard 2777 S. Crystal Drive Arlington VA 22202

Attn: Ms. Julie Chao, Insecticide-Rodenticide Branch

Re: Current Labeling and CSF Alternate Formulation #2

Product: Counter Assault Bear Deterrent

EPA Reg. No.: 55541-2

Company: Bushwacker Backpack and Supply Company, DBA Counter Assault

Dear Mr. Hebert:

On February 11, 2008, EPA approved Alternate Formulation #2 for Counter Assault Bear Deterrent, EPA Reg. No. 55541-2. The submission for this formulation included a spray pattern study which showed a slightly shorter spray time and an increased distance for the alternate formulation. EPA's Feb 11 letter requested that Counter Assault submit revised labeling reflecting the time and distance change.

Counter Assault must complete several additional steps before it can convert to the alternate formulation, including obtaining approval from California and Canada. We anticipate that it could be a year before the company is ready to convert to the new formula. Therefore, it is not appropriate to change the spray time and distance on the label until the company is ready to convert to the new formula. Likewise, we do not want to withdraw Alternate Formula #2 as it took over a year to obtain approval, and we cannot seek approval in California and other regulatory entities if we do not have an EPA approved formula.

Instead, we request that EPA allow the current time/distance (230 g can: 7.2 seconds/30 feet, 290g can: 9.2 seconds/32 feet) to remain on the labeling based on the following commitment:

Bushwacker Backpack and Supply Company, DBA Counter Assault, commits that it will submit the spray time/distance changes as an amendment and obtain EPA approval for the labeling amendment prior to converting to Alternate Formula #2.

If you have any questions or concerns, please call me at (301) 680-7971.

Sincerely,

Cristina Griffin

Agent for Counter Assault

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES

March 21, 2008

Pride Johnson Counter Assault 120 Industrial Court Kalispell, MT 59901

Dear Mr. Johnson:

Subject:

Submission of revised label Counter Assault Bear Deterrent EPA Registration No. 55541-2

Your e-mail submission dated 3/4/08

Decision # 447 299
300
5-894 742

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable with the following comments:

- On the insert card, header card, and any other instances where it appears, change "EPA # 55541-2" to "EPA Registration # 55541-2." "EPA Reg. # 55541-2" or "EPA Reg. No. 55541-2" is also acceptable.
- For the 8.1 ounce (230 g) product size, change all duration-of-spray claims from 7.2 to
 7.1 seconds so the statement reads, "The canister empties in approximately 7.1 seconds."
 This change is based on data submitted to the Agency by Counter Assault, and was also
 required in Agency correspondence dated 2/11/08.
- For the 10.2 ounce (290 g) product size, change all duration-of-spray claims from 9.2 to 8.2 seconds so the statement reads, "The canister empties in approximately 8.2 seconds."
 This change is based on data submitted to the Agency by Counter Assault, and was also required in Agency correspondence dated 2/11/08.
- On both the 8.1 ounce and 10.2 ounce canisters, under Storage and Disposal, add the following, bolded text so the statement reads:

DISPOSAL: DO NOT PUNCTURE OR INCINERATE!

Non-Refillable Container. Do not reuse or refill this container. Offer for recycling if available.

If empty: Press valve to release...

 The alternate brand names "Magnum 290 Bear Deterrent" and "Magnum 290" are acceptable. Please note, however, that only labels bearing the primary brand name, "Counter Assault Bear Deterrent," will be stamped.

A stamped copy is enclosed for your records. Please submit two copies of your final printed labeling before you release the product for shipment. Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). If you have any questions, please Julie Chao at (703) 308-8735 or chao.julie@epa.gov.

Regards,

John Hebert

Insecticide-Rodenticide Branch Registration Division (7505P)

Enclosure

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

DANGER:

May cause irreversible eye damage if sprayed in the eye at close range. Contact through touching or rubbing eyes may result in substantial but temporary eye injury. Strongly irritating to nose and skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID:

IF IN EYES. Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses after the first 5 minutes then continue rinsing eye. Call poison control center or doctor for treatment advice. Have product container with you when calling or going for treatment. For emergency medical treatment information call 1-800-535-5053.

IF ON SKIN OR CLUTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor immediately for treatment advice.

PHYSICAL OR CHEMICAL HAZARDS:

Extremely flammable. Contents under pressure. Keep away from fire, sparks and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 139 F may cause bursting.

STORAGE & DISPOSAL

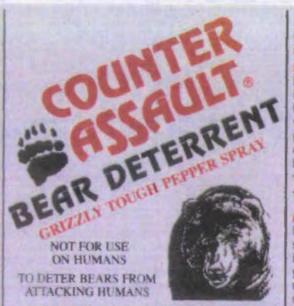
STORAGE STORE IN A COOL DRY PLACE INACCESSIBLE TO CHILDREN AND PETS. Do not store in places where the temperature is above 120°F nor below 32°F. Do not store in hot vehicle or in direct sunlight.

DISPOSAL: DO NOT PUNCTURE OR INCINERATE If empty: Press valve to release all pressure then place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions.

Disclaimer. To the extent allowable by law. Counter Assault shall not be liable for damage, injury, loss, direct or consequential including death arising out of the use of, or inability to use this product.

ACCEPTED with COMMENTS In EPA Letter Dated:

MAR 2 1 2008
Under the Pederal Insecticide,
Fungicide, and Rodsmicide Act,
as amended, for the pesticide
registered under RPA Reg. No.



DANGER

DO NOT SEEK OUT ENCOUNTERS WITH BEARS. THIS PRODUCT IS A BEAR ATTACK DETERRENT WHICH MAY PROTECT USERS IN SOME UNEXPECTED CONFRONTATIONS WITH BEARS BUT MAY NOT BE EFFECTIVE IN ALL SITUATIONS OF PREVENT ALL INJURIES. READ THIS ENTIRE LABEL BEFORE TAKING THIS PRODUCT INTO AREAS WHERE BEARS MIGHT BE ENCOUNTERED. SEE SIDE PANELS FOR FIRST AID AND PRECAUTIONARY STATEMENTS.

Active Ingredient:

Capsaicin and related capsaicinoids 2.0%
Other Ingredients 98.0%
TOTAL 100.0%

*Derived from Oleocesin of Capsicum

Manufactured by:
Bushwacker Backpack and Supply Co., Inc.,
dba COUNTER ASSAULT
120 Industrial Court, Kalispell, MT 59901
1-800-695-3394 • (406) 257-4740

CHEMICAL EMERGENCY: 1-800-535-5053

NET CONTENTS: 8.1 ounces (230g)

EPA Registration #55541-2

EPA Est No. 055541-MT-001

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: This product may be used only to deler bears which are attacking or appear likely to attack humans. Do not spray this product on objects, tents, or humans; such use has no deterrent effect on bears. Do not seek out encounters with bears or intentionally provoke them. Keep safety clip in place except when practicing with or using the product. Do not eat or allow to be eaten any lood or feed materials which may have become contaminated with this product.

This product has a range of up to 30 feet (9 meters). The canister empties in approximately 7.2 seconds.

APPLICATION DIRECTIONS: Special procedures must be followed to arm the container apply the product and restore the safety clip to disarm the container. Before taking this product into bear country, read the directions below and familiarize yourself with these procedures. If you test-fire this container, make sure the wind is at your back and depress actuator tab for no more than half a second. Do not test-fire in area inhabited by bears. If test-fired, clean nozzle and can with soap and water to remove residue from can. If you have not used this product before, you should obtain a Counter Assault training can and practice with it until you can perform these activities quickly and accurately.

To Arm and Apply

Designed for one-hand operation. Place forelinger through hole in handle with thumb on safety clip curl. With thumb, pull safety clip straight back and off (fig. 1).

Depress actuator tab for burst of spray (fig 2). Aim at tace and eyes of bear Depress actuator tab for 1-2 seconds in order to create a barrier of spray between you and the bear. Stop to evaluate the impact of wind and other factors and adjust your safety Clip aim if needed before spraying again.

Te Disarm

Replace safety clip by pushing firmly with thumb until audible "snap" is heard (fig 3). Check to see if safety is completely in place. No gap should be visible between actuator handle and safety clip.





8.1 oz bear Spray

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

DANGER:

May cause irreversible eye damage if sprayed in the eye at close range Contact through touching or rubbing eyes may result in substantial but temporary eye injury. Strongly irritating to nose and skin. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID:

IF IN EYES Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses after the first 5 minutes then continue rinsing eye. Call poison control center or doctor for treatment advice. Have product container with you when calling or going for treatment. For emergency medical treatment information call 1-800-535-5053.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor immediately for treatment advice.

PHYSICAL OR CHEMICAL HAZARDS:

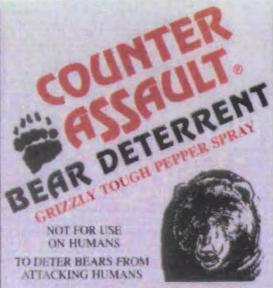
Extremely flammable. Contents under pressure Keep away from fire, sparks and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

STORAGE & DISPOSAL

STURAGE STORE IN A COOL DRY PLACE INACCESSIBLE TO CHILDREN AND PETS. Do not store in places where the temperature is above 120°F nor below 32°F. Do not store in not vehicle or in direct sunlight.

HEMPOSAL: DO NOT PUNCTURE OR INCINERATE! HEMPTY: Press valve to release all pressure then place in trash or offer for recycling if available. Il partly filled; Call your local solid waste agency for disposal instructions.

Disclaimer: To the extent allowable by law. Counter Assault shall not be liable for damage, injury loss direct or consequential including death arising out of the use of, or inability to use this product.



REEP OUT OF REACH OF CHILDREN DANGER

DO NOT SEEK OUT ENCOUNTERS WITH BEARS. THIS PRODUCT IS A BEAR ATTACK DETERRENT WHICH MAY PROTECT USERS IN SOME UNEXPECTED CONFRONTATIONS WITH BEARS BUT MAY NOT BE EFFECTIVE IN ALL SITUATIONS OR PREVENT ALL INJURIES. READ THIS ENTIRE LABEL BEFORE LAKING THIS PRODUCT INTO AREAS WHERE BEARS MIGHT BE ENCOUNTERED. SEE SIDE PANELS FOR FIRST AND AND PRECAUTIONARY STATEMENTS.

Active Ingredient:

Capsaicin and related capsaicinoids 2.0%
Other Ingredients 98.0%
TOTAL 100.0%

*Derived from Oleoresin of Capacum

Manufactured by:
Bushwacker Backpack and Supply Co., Inc.,
dba COUNTER ASSAULT
120 Industrial Court, Katopell, MT 59901
1-800-695-3394 • (406) 257-4740
CHEMICAL EMERGENCY 1-800-535-5053

NET CONTENTS: 10.2 ounces (290g)

EPA Registration #55541-2

EPA En No. 055541-MT-001

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS. This product may be used only to deter bears which are attacking or appear likely to attack humans. Do not spray this product on objects, tents, or humans, such use has no deterrent effect on bears. Do not seek out encounters with hears or intentionally provoke them. Keep safety clip in place except when practicing with or using the product. Do not eat or allow to be eaten any food or feed materials which may have become contaminated with this product.

This product has a range of up to 32 feet (10 meters). The canister empties in approximately 9.2 seconds.

APPLICATION DIRECTIONS: Special procedures must be followed to arm the container, apply the product and restore the safety clip to disarm the container. Before taking this product into bear country, read the directions below and familiarize yourself with these procedures. If you test-fire this container, make sure the wind is at your back and depress actualor tab for no more than half a second. Do not test-fire in area inhabited by bears. If test-fired, clean nozzle and can with soap and water to remove residue from can. If you have not used this product before, you should obtain a Counter Assault training can and practice with it until you can perform these activities quickly and accurately.

To Arm and Apply

Designed for one hand operation. Place forefinger through hole in handle with thumb on safety clip curl. With thumb, pull safety clip straight back and off (fig 1).

Depress actuator tab for burst of spray (fig 2). Aim at face and eyes of bear Depress actuator tab for 1-2 seconds in order to create a barrier of spray between you and the bear Stop to evaluate the impact of wind and other factors and adjust your aim if needed before spraying again.

Yo Disarm

Replace safety clip by pushing firmly with thumb until audible 'snap' is heard (fig 3). Check to see it safety is completely in place. No gap should be visible between actuator handle and safety clip.







deter bears from attacking humans Heeds no shaking Grizzly Tough¹¹ Pepper Spray Heeds no shaking



Sprays to 30 feet; 7.2 seconds of spray time (230 g canister) Sprays to 32 feet; 9.2 seconds of spray time (290 g canister)



120 Industrial Court Kalispell, MT 59901 1-800-695-3394 7 22031 41230 9

Front track

original@counterassault.com

FREDUCED BY A GREZZLY ENCOUNTER SURVIVOR!

In the early 1980's, bear biologists were researching effective bear deterrents. The result of this research was the development of an atomized spray and led to the creation of Counter Assault.

Pride Johnson, President & Chemist of Counter Assault successfully survived a grizzly encounter with Counter Assault Bear Deterrent. The encounter was immediately stopped.

COUNTER ASSAULT BEAR DETERRENT PEPPER SPRAY

USE EESTINGTIDIES: This product may be used only to defer been which are attanking or appear Meth to attank hamans. Do not spray this product on objects, bunks, or humans or intentionally provide them. Keep safety clip in place except when practicing with or using the product. Do not set or allow to be eaten any food or feed metertals which may have become contaminated with this product.

This product has a range of up to 30 test (9 meters) (230g containe) and 32 feet (10 meters) (230g containe). The contains emption in approximately 7.2 expects (230g containe) and 0.2 projects (200g containe).

APPLICATION DIRECTIONS: Special procedures must be followed to arm the container, apply the product and restore the safety clip to disarm the container. Before taking this product into beer country, read the directions below and familiarize yourself with these procedures. If you test-fire this container, make sure the wind is at your beck and depress actuator table for none than half a second. Do not test-fire in area inhebited by beers. If test-fired, clean nozzle and can with soap and water to remove residue from can. If you have not used this product before, you should obtain a Counter Assault training can and practice with it until you can perform the activities quickly and accurately.

TO ARM AND APPLY: Designed for one-hand operation, Place forefinger through hole in handle with thumb on safety clip our. With thumb, pull safety clip straight back and off (fig. 1). Depress actuator tab for burst of spray (fig. 2). After at face and eyes of beer. Depress actuator tab for 1-2 accords in order to create a barrier of spray between you and the beer. Stop to evaluate the impact of wind and other factors and adjust your aim if needed before

screying again.

TO DESARRIE Replace safety cip by pushing firmly with thumb until audible "snap" is heard (fig 3). Check to see if safety is completely in place. No gap should be visible between actuator handle and safety clip.



May cause irreversible eye damage if sprayed in the eye at close rarge. So, on sidn, or on clothing or rubbing eyes may result in substantial but temporary eye injury. Strongly irritating to nose and sidn. Do not get in eyes, on sidn, or on clothing. Week thoroughly with some and water after handling. Remove contaminated clothing and week clothing before reuse.

FIN EYES: Hold eye open and rinse clowly and gently with water for 15-20 minutes. Remove contact lenses after the first 5 minutes, then confirms rinsing eye. Call poison control center or doctor for treatment advice. Have product container with you when calling or going for treatment and receive the confirming the confirmation of container with you when calling or going for the confirming of the confirming of container with your when calling or going for the confirming of the confirming o

Extremely flormeable. Contents under pressure. Keep every from time, sparks and healed surfaces. Do notpuncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

STORAGE & DESPOSAL

STORAG





John Hebert/DC/USEPA/US 03/08/2008 10:13 AM To "Pride Johnson" <pri>pride@counterassault.com>

C

bcc Julie Chao/DC/USEPA/US

Subject Re: Additional labeling items requested

Pride - I will try to have these reviewed by the March 21.

Regards, John Hebert

"Pride Johnson" <pride@counterassault.com>



"Pride Johnson"

pride@counterassault.com>

To John Hebert/DC/USEPA/US@EPA

CC

03/04/2008 01:31 PM

Subject Additional labeling items requested

Dear John,

Attached please find the current labels for the 8.1 oz and 10.2 oz canisters and the header card you requested in your conversation with Kirsten this morning. These, along with the insert card you already have, consist of all of our bear deterrent labeling.

If you have any questions or need anything further, please call us on our cell phone at $406-261\ 8032$.

Sincerely,

Pride Johnson







header card.jpg 8.1 oz bear spray.jpg 10,2 oz bear spray.jpg



John Hebert/DC/USEPA/US 03/21/2008 09:42 AM To Julie Chao/DC/USEPA/US@EPA

CC

bcc

Subject Fw: labeling for Counter Assault

--- Forwarded by John Hebert/DC/USEPA/US on 03/21/2008 09:42 AM ----



"Pride Johnson" <pride@counterassault.com>

02/14/2008 07:53 PM

To John Hebert/DC/USEPA/US@EPA

cc Meredith Laws/DC/USEPA/US@EPA

Subject labeling for Counter Assault

Mr. Heberts,

Per your email of February 1, 2008, I have attached a proof of our new inert card. We are about out of stock and need to reorder ASAP. We had already placed an order with the printer based on your earlier emails, but it had not gone to print and we were able to stop it and make revisions based on your lastest email. We have not changed any of our other labeling yet. Due to space limitations on this insert card, we opted not to include a picture or the phrase "Delivers a large amount of spray in an adequate amount of time". We might add these in the future if we make packaging changes. We also left off the phrase "Notice - no blood, no guts" as we decided that sounded unprofessional.

We appreciate your promt attention to this since we need to place an order now.

Best regards,



Pride Johnson CounterAssault_2-14-08_Proof.pdf



John Hebert/DC/USEPA/US 03/19/2008 02:20 PM

To Julie Chao/DC/USEPA/US@EPA

C

bcc

Subject Fw: Reply to October 15, 2007 letter

more...regarding number 5, can you look into that when you get a chance? ask me if you need more information.

john

--- Forwarded by John Hebert/DC/USEPA/US on 03/19/2008 02:19 PM ---



John Hebert/DC/USEPA/US 02/01/2008 10:17 AM

To "Pride Johnson" <pride@counterassault.com>

CC Meredith Laws/DC/USEPA/US@EPA

Subject Re: Fw: Reply to October 15, 2007 letter

Pride - I hope all is well. I think I'm finally able to respond to all your labeling questions:

- 1. Use of the phrase, "Developed in Conjunction with the University of Montana" is acceptable.
- We cannot substantiate if your product is the "original" bear pepper spray. While it is the first bear spray to have an EPA registration, that does not necessarily mean that it is the "original" product. Therefore, we will accept the following phrase "One of the original bear pepper sprays".
- The proposed phrases in number 4 of your Oct. 15, 2007 letter are acceptable.
- 4. The proposed phrases in number 5 of your Oct. 15, 2007 letter are not acceptable. Generally, the only endorsement from an outside group we allow on labels is the Good Housekeeping Seal. We do not allow other endorsements because it can imply that one product is safer/more efficacious than another product. Also, in most cases we don't know anything about the endorser or what their relationship to the registrant is.
- 5. We will contact UDAP and have them remove any US Govt. employee endorsements, testimonials, etc. from their labeling.

I just want to mention that I had our internal labeling committee weigh-in on items 1-4. I believe I have addressed all your issues/questions. Please let me know if I haven't. You can submit revised labeling incorporating all the issues we've discussed at your convenience.

Regards, John Hebert 703-308-6249

"Pride Johnson" <pri>pride@counterassault.com>



"Pride Johnson" <pri><pride@counterassault.com</pr>

01/11/2008 05:53 PM

To John Hebert/DC/USEPA/US@EPA

cc Meredith Laws/DC/USEPA/US@EPA

Subject Re: Fw: Reply to October 15, 2007 letter



Mr. Hebert,

Thank you for you response and approving the "magnum" issue.

Referring to \$1 regarding having a claim from a government employee, it appears from the EPA website that the March 2007 submission ONLY added an additional size can and did not make any other changes to existing approved supplemental labeling. By your response, do you mean the booklet approved on 7 19-04 is not a currently approved supplemental label? If so, when was UDAP notified that this was no longer approved and that it should be removed from the market? The booklet with the government employee endorsement is still being sold with the product. From the information published on the EPA website, it does not agree with your statement that the booklet is not an approved supplemental label. I do not feel that this issue has been resolved by your response and expect a further reply to this issue.

Looking forward to you addressing this and the other responses with the original letter and booklet.

Pride

---- Original Message ---From: <Hebert.John@epamail.epa.gov>
To: "Pride Johnson" <pride@counterassault.com>
Sent: Friday, January 11, 2008 12:36 PM
Subject: Re: Fw: Reply to October 15, 2007 letter

> Mr. Johnson - Sorry, I don't have complete answers to items 3-5 from my > Nov. 2, 2007 email. After discussion with some of my colleagues it was > decided that this needed to be discussed at an internal labeling > committee (composed of senior label reviewers) meeting. I think they > should be meeting in the next week or so. > Regarding other issues from my email and your Nov. 15, 2007 letter I > have the following comments: > 1. The latest stamped/approved label for UDAP label (dated March 5, > 2007) does not have the Park Service employee quote. I apologize for > our inconsistency but we cannot allow your label to carry a similar > claim for the same time period it was allowed on UDAP's label. > 2. The alternate brand names "Magnum 290 Bear Deterrent" and "Magnum > 290" are acceptable. > I hope to have answers for all your questions in the next few weeks. > Regards, > John Hebert > 703-308-6249

"Pride Johnson" <pride@countera

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ssault.com>
                                                                         To
                                       John Hebert/DC/USEPA/US@EPA
               01/04/2008
                                                                        CC
               05:08 PM
                                                                   Subject
                                       Re: Fw: Reply to October 15, 2007
                                       letter
> Mr. Hebert,
> Thank you for your timely response.
> Pride
> ---- Original Message ---
> From: <Hebert.John@epamail.epa.gov>
> To: "Pride Johnson" <pride@counterassault.com>
> Cc: <laws.meredith@epa.gov>
> Sent: Friday, January 04, 2008 2:22 PM
> Subject: Re: Fw: Reply to October 15, 2007 letter
>> Mr. Johnson - My goal is to have a response to you by the January 11.
>>
>> Regards,
>> John Hebert
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>
               "Pride Johnson"
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                <pride@counteras</pre>
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                sault.com>
                                                                          To
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                                         John Hebert/DC/USEPA/US@EPA
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>
                01/03/2008 12:32
                                                                          CC
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>
                PM
                                         Meredith Laws/DC/USEPA/US@EPA
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>
                                                                    Subject
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                                         Fw: Reply to October 15, 2007
>
                                          letter
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>> Mr. Hebert,
>>
>> With the Holidays over, I look forward to you responding to my
>> e-mail and attachment.
>> Thank you.
>> Pride Johnson
>> ---- Original Message ----
>> From: "Pride Johnson" <pride@counterassault.com>
>> To: <Hebert.John@epamail.epa.gov>
>> Sent: Tuesday, December 11, 2007 8:43 AM
>> Subject: Re: Reply to October 15, 2007 letter
>>
>>
>>>
>>> Mr. Hebert,
>>> I've been waiting for your reply to the attachment since mid-November
>> when
>>> I
>>> realize today that you never received this letter. I was traveling
>>> weeks and then my wife had surgery upon our return and I've been out
>> of
>>> the
>>> office, off and on, for almost a month. My secretary was to have
>>> this letter to you. Life is hectic at times.
>>> Pride Johnson
>>> President/Chemist
>>>
>>>>
>>>> ---- Original Message ----
>>>> From: <Hebert.John@epamail.epa.gov>
>>>> To: <original@counterassault.com>
>>>> Cc: <laws.meredith@epa.gov>
>>>> Sent: Monday, November 05, 2007 1:51 PM
>>>> Subject: Reply to October 15, 2007 letter
>>>>
>>>>
>>>>>
>>>>>
>>>> Mr. Johnson: Regarding your Oct. 15, 2007 letter on labeling
```

> issues >> for >>>> Counter Assault Bear Deterrent (EPA Reg. No. 55541-2), I have the >>>> following comments: >>>> 1. The phrase "Counter Assault Bear Deterrent disperses large >>>> of active ingredients in a sufficient amount of time" is > acceptable. >>>>> >>>> 2. The phrase "Counter Assault Bear Deterrent works on all bear >>>> species* is acceptable. >>>> 3. I will have to check with our internal label group for > clearance >> of >>>> the phrase "Developed in conjunction with the University of >>>> I'm not questioning whether the University was involved in the >>>> development of your product, I just want to make sure that we do >>>> consider it an unacceptable endorsement. I will also check with >>>> product managers on "original". Generally, we try to stay away >>>> claims like original because we are generally not in a position to >>>> substantiate that type of claim. >>>> 4. Again, I will have to check on this one with our internal >> labeling >>>> group. >>>>> >>>> 5. Same as #4. >>>>> >>>> 6. We will accept your email address on the labeling. Our policy >> is to >>>> not allow websites on labeling. When websites are listed on >> labeling it >>>> legally becomes part of the label and requires our review. We are >>>> that many labels do carry websites and we are correcting this as we >>>> approve labeling amendments. I will require competitor products >>>> violate this policy to delete the website address. >>>> 7. It is not appropriate to have quote/opinion/endorsement >>>> to an EPA employee on a pesticide label. I also agree that the >>>> applies to any U.S Federal government employee. We will check your >>>> competitor product labels for violations of this policy. >>>> 8. The alternate brand name that you propose would be acceptable > if >>>> qualified it with "brand". In other words the following would be >>>> acceptable: "Magnum Brand 290" and "Magnum Brand 290 Bear >> Deterrent." >>>> "Fires" is not an appropriate description of the mechanism of these >> bear

74

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>>>> deterrent products. Other product labels with "fires" will be told
>> to
>>>> change that wording to "sprays."
>>>> 9. The phrase, "Developer of high emission "atomized" fire
>> extinguisher
>>>> style pepper spray used in bear deterrents is acceptable.
>>>> 10. The phrase, "Tough 600 Denier Polyester Holster" is
> acceptable.
>>>> You can submit amended labeling at your convenience with the
>> language
>>>> discussed above. You may want to wait until all I'm able to
> resolve
>> all
>>>> the issues. As I mentioned previously, I have told our branch
>>>> (copied above) about your concerns. I hope to be in touch with you
>>>> soon.
>>>> Regards,
>>>> John Hebert
>>>>>
>>>>
>>>>>
>> (See attached file: Counter Assault's reply to 11-05-2007 Email.pdf)
>
```



DATA PACKAGE BEAN SHEET

Date: 16-Jan-2008

Page 1 of 3

Decision #: 376199

DP #: (348429)

PRIA

Parent DP#:

	***	Registration	Information	* *	*
Registration:	55541-2 - COUNTER	ASSAULT BEA	R DETERRENT		

negistration.	3554 1-2 - COUNTEN AS	SAUL I BEAR DE	TENNENT		-
Company:	55541 - BUSHWACKER BACK	CPACK & SUPPLY CO) <u>.</u>		
Risk Manager:	RM 07 - John Hebert - (703) 30	08-6249 Room#PY1 S	-7227		
k Manager Reviewer:	Daniel Peacock DPEACOCK				
Sent Date:		Calculated Due Date	: 12-Nov-2007	Edited	Due Date:
Type of Registration:	Product Registration - Section	3			
Action Desc:	(R34) NON-FAST-TRACK (INC	CLUDES CHANGES T	O PRECAUTION	IARY LABEL STATEME	N.
Ingredients:	070701, Capsaicin(2%)				
	* * * Da	ta Package Inf	ormation *	**	
Expedite:	Yes No	Date Sen	: 16-Jan-2008	_	Due Back:
DP Ingredient:	070701, Capsaicin				
DP Title:					
CSF Included:	○ Yes ● No Label	Included: Yes	No Pare	ent DP #:	
Assigned To	0	Party for	Date Out		
		Date In	Date Out		
Organization: RD / II	RB			Last Possible Science	Due Date: 12-Jan-2008
Team Name: Efficad	cy (IAB)			Science	Due Date:
eviewer Name: Jacob	s, William			Sub Data Package	Due Date:
ntractor Name:					

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Printed on Page 3

* * * Data Package Instructions * * *

Dear Bill,

Here is the done spray pattern data for this product (55541-2), which had to be redone because they did not follow the standard protocol.

They had to redo the data originally because they changed over 1/2 of their formula. That included a new-non-food inert thet was rejected at first, then accepted, based on the low exposure.

Endosures:

- 1. app form
- 2. cover letter
- 3. data
- 4. background information

If you have any questions, please contact me.

The Due Date is Feb 11, 2008.

DP#: (348-	429)	*** Add	Page Data Packag	The second second second	cision * * *	D	ecisio	on#: (376199)
DP#		Division/Branch	Date Sent	Date Due	Instructions?	CSF	100	label
339786	RD / IRB		10-May-2007	11-Jun-2007	Yes No	Yes 1	Vo	Yes No
339786	RD/IRB		10-May-2007	11-Jun-2007	Yes No	Yes 1	No	Yes No

DP#: (348429)

Page 2 * * * Studies Sent for Review * * *

Decision#: (376199)

Guideline

MRID Status MRID 47308201

Citation Reference

Johnson, P. (2007) Counter Assault Bear Deterrent: Spray Pattern Study: 8.1 Ounce (230g) and 10.2 Ounce Size (290g). Unpublished study prepared by Bushwacker Backpack & Supply Co. 7 p.

Memorandum Cond. Data

Date: 12/28/07

To: ______, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: fully accepted submission

partially accepted submission

☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

December 27, 2007

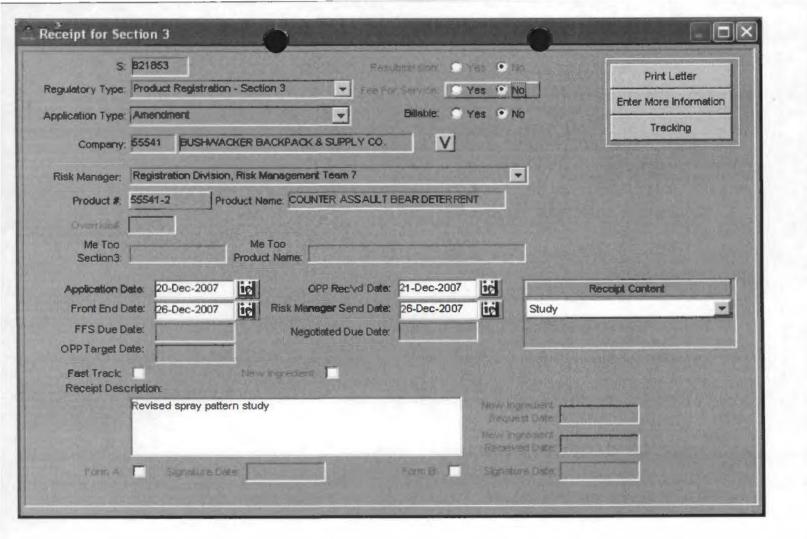
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

BUSHWACKER BACKPACK & SUPPLY CO. 120 INDUSTRIAL COURT KALISPELL, MT 59901

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 21-DEC-07. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.





December 20, 2007

Document Processing Desk (RESUB)
Office of Pesticide Programs (7504P)
Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive, Room S 4900
Arlington VA 22202

Attn: John Hebert, PM 7/ Dan Peacock, Insecticide-Rodenticide Branch

Re: Resubmission of spray pattern study as per your request and letter of

October 24, 2007

Product: Counter Assault Bear Deterrent

EPA Reg. No.: 55541-2

Company: Bushwacker Backpack and Supply Company,

DBA Counter Assault

Data Transmittal Letter Pursuant to FIFRA Section 3

Dear Mr. Hebert/Mr. Peacock:

On behalf of Bushwacker Backpack and Supply Company, DBA Counter Assault, I am submitting three copies of the following study as requested for the product Counter Assault Bear Deterrent, EPA Reg. No. 55541-2.

 Volume 1 of 1 Counter Assault Bear Deterrent EPA Reg. No. 55541-2 Spray Pattern 8.1 ounce (230 grams) and 10.2 ounce (290 gram) size, December 14, 2007

MRID # 47308201

If you have any questions regarding this submission, please call me at (301) 680-7971 or email cgriffin@delta-ac.com.

Sincerely,

Cristina Griffin

Agent for Counter Assault

cc: Pride Johnson, Counter Assault

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the

necessary forms. Send comments regarding burden estimate or any other aspect burden to: Director, OPPE Information Management Division (2137), U.S. Environ Do not send the completed form to this address.		
Certification with Respec	t to Citation of	Data
Applicant's/Registrant's Name, Address, and Telephone Number Bushwacker Backpack & Supply Co., Inc., DBA Counter Assault c/o Delta Analy 12510 Prosperity Dr., Suite 160, Silver Spring, MD 20904, 301-680-7971		EPA Registration Number/File Symbol 55541-2
Active Ingredient(s) and/or representative test compound(s) Capsaicin and related capsaicinoids		Date December 20, 2007
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 1: Domestic outdoor	58)	Product Name Counter Assault Bear Deterrent
NOTE: If your product is a 100% repackaging or another purchased EPA-register submit this form. You must submit the Formulator's Exemption Statement (EPA		for all the same uses on your label, you do not need to
I am responding to a Data-Call-In Notice, and have included with this for (the Data Matrix form should be used for this purpose).	orm a list of compani	ies sent offers of compensation
SECTION I: METHOD OF DATA SUP	PORT (Check on	e method only)
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Oata Matrix form should be used for this purpose).	the selective	ne selective method of support (or cite-all option under method), and have included with this form a lata requirements (the Data Matrix form must be
SECTION II: GENERAL	OFFER TO PAY	
[Required if using the cite-all method or when using the cite-all option under the s I hereby offer and agree to pay compensation, to other persons, with re SECTION III: CER	egard to the approva	
I certify that this application for registration, this form for reregistration, or this application for registration, the form for reregistration, or the Data-Call-In response method is indicated in Section I, this application is supported by all data in the Agidentical or substantially similar product, or one or more of the ingredients in this under the data requirements in effect on the date of approval of this application if similar composition and uses. I certify that for each exclusive use study cited in support of this registration of the written permission of the original data submitter to cite the study. I certify that for each study cited in support of this registration or reregistration (b) I have obtained the permission of the original data submitter to use the study have expired for the study; (d) the study is in the public literature; or (e) I have no to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(E) and terms of compensation, if any, to be paid for the use of the study. I certify that in all instances where an offer of compensation is required, copies accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and such evidence to the Agency upon request, I understand that the Agency may iniconformity with FIFRA. I certify that the statements I have made on this form and all attachments knowingly false or misleading statement may be punishable by fine or impri	te. In addition, if the pency's files that (1) product; and (2) is a the application sough reregistration, that that is not an exclusin support of this applified in writing the case of all offers to pay will be submitted to tiate action to deny, as to it are true, accurately files.	cite-all option or cite-all option under the selective concern the properties or effects of this product or an type of data that would be required to be submitted that the initial registration of a product or identical or a many the original data submitter or that I have obtained sive use study, either: (a) I am the original submitter; colication (c) all periods of eligibility for compensation ompany that submitted the study and have offered (1) to commence negotiations to determine the amount compensation and evidence of their delivery in the Agency upon request. Should I fail to produce cancel or suspend the registration of my product in urate, and complete. I acknowledge thet any
Signature Rell-	Date 12/20/07	Typed or Printed Name and Title Cristin Griffin Agent for Bushwacker Backpack and Supply Co., Inc., DBA Counter Assault

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		DATA MATRIX	(
Date December 20, 2007			EPA Reg No./File Symbol 55541-2	Page 1 of 4		
Applicant's/Registrant's Name & Add	ress Bushwacker Backpack & Supply Co., Inc., Di c/o Delta Analytical Corp. 12510 Prosperity Dr., Suite 160, Silver Spring	Product Counter Assault Bear Deterrent				
Ingredient Capsaicin and related c	apsaicinoids					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
PRODUCT CHEMISTRY: Counter Assault Bear Deterrent						
330.1550	Product identity and composition	44336902	Bushwacker Backpack & Supply Co., Inc.	OWN		
830.1600	Description of materials used to produce the product	44336902	Bushwacker Backpack & Supply Co., Inc.	OWN		
830.1620	Description of production process	44336902	Bushwacker Backpack & Supply Co., Inc.	OWN		
830.1650	Description of formulation process	44336902	Bushwacker Backpack & Supply Co., Inc.	OWN		
830.1670	Discussion of formation of impurities	44336902	Bushwacker Backpack & Supply Co., Inc.	OWN		
830.1700	Preliminary analysis	NA	NA	NA		
830.1750	Certified limits	See CSF	Bushwacker Backpack & Supply Co., Inc.	OWN		
830.1800	Enforcement analytical method	44336901	Bushwacker Backpack & Supply Co., Inc.	OWN		
830.1900	Submittal of samples	NA	NA	NA		
830.6302	Color	NA	NA	NA		
830.6303	Physical state	44336902	Bushwacker Backpack & Supply Co., Inc.	OWN		
830.6304	Odor	NA	NA	NA		
830.6313	Stability to normal and elevated temperature, metals, and metal ions	NA	NA	NA		
Signature Creature.	2-11-		Name and Title Cristina Griffin Agent for Bu and Supply Co., Inc.	ishwacker Backpack	Date 12/20/07	

EPA Form 8570-35(9-97) Electronic and Paper versions available. Submit only Paper version.

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		DATA MATRIX	(
Date December 20, 2007		EPA Reg No /File Symbol 55541-2	Page 2 of 4		
Applicant's/Registrant's Name & Address Bushwacker Backpack & Supply Co., Inc., DBA Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Dr., Suite 160, Silver Spring, MD 20904		Product Counter Assault Bear Deterrent			
ngredient Capsaicin and related	capsaicinoids				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
330.6314	Oxidation/reduction: chemical incompatibility	NA	NA	NA	
330.6315	Flammability	44558301	Bushwacker Backpack & Supply Co., Inc.	OWN	
330.6316	Explodability	NA	NA	NA	
330.6317	Storage stability	NA	NA	NA	to be submitted
330.6319	Miscibility	NA	NA	NA	
330.6320	Corrosion characteristics	NA	NA .	NA	to be submitted
830.6321	Dielectric breakdown voltage	NA	NA	NA	
830.7000	pH	NA	NA	NA	
830.7050	UV/visible absorption	NA	NA	NA	
830.7100	Viscosity	NA	NA	NA	
830.7200	Melting point/melting range	NA	NA	NA	
830.7220	Boiling point/boiling range	NA	NA	NA	
830.7300	Density/relative density/bulk density	44336902	Bushwacker Backpack & Supply Co., Inc.	OWN	
830.7370	Dissociation constant in water	NA	NA	NA	
Signature Justina	2-11.		Name and Title Cristina Griffin Agent for Bu and Supply Co., Inc.	shwacker Backpack	Date 12/20/07

Form Approved OMB No. 2070-0060

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		DATA MATRIX	X .		
Date December 20, 2007 Applicant's/Registrant's Name & Address Bushwacker Backpack & Supply Co., Inc., DBA Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Dr., Suite 160, Silver Spring, MD 20904			EPA Reg No./File Symbol 555	Page 3 of 4	
			Product Counter Assault Be		
ngredient Capsaicin and related	d capsaicinoids				'
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
330.7520	Particle size, fiber length, and diameter distribution	NA	NA NA	NA	
330.7550	Partition coefficient (n-octanol/water), shake flask method	NA	NA	NA	
830.7560	Partition coefficient (n-octanol/water), generator column method	NA	NA	NA	
330.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography	NA	NA	NA	
830.7840	Water solubility: column elution method; shake flask method	NA	NA	NA	
830.7850	Water solubility: generator column method	NA	NA	NA	
830.7950	Vapor pressure	NA	NA	NA	
Signature Jatima	R-11.		Name and Title Cristina Griffin and Supply Co., Inc.	Agent for Bushwacker Backpack	Date 12/20/07

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		DATA MATRIX				
Date December 20, 2007			EPA Reg No./File Symbol 55541-2		Page 4 of 4	
Applicant's/Registrant's Name & Address Bushwacker Backpack & Supply Co., Inc., DBA Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Dr., Suite 160, Silver Spring, MD 20904			Product Counter Assault Bear Deterrent			
Ingredient Capsaicin and related	d capsaicinoids					
Guideline Reference Number	eference Number Guideline Study Name		Submitter	Status	Note	
PRODUCT PERFORMANCE		E-S				
96-1	Bear Deterrent	427676-06		OLD		
96-1	Bear Deterrent	00145063		OLD		
96-1	Bear Deterrent	Accession# 254706		OLD		
96-1	Bear Deterrent	Accession# 250625		OLD		
NA .	Counter Asault Bear Deterrent: Spray Pattern 8.1 ounce and 10.2 ounce size	46136704	Bushwacker Backpack & Supply Co., Inc.	OWN		
NA	Counter Assault Bear Deterrent EPA Reg. No. 55541-2 Spray Pattern, 8.1 ounce (230 grams) and 10.2 ounce (290 grams) size	47066801	Bushwacker Backpack & Supply Co., Inc.	OWN		
NA	Counter Assault Bear Deterrent: EPA Reg. No. 55541-2, Spray Pattern Study, 8.1 ounce (230 grams) and 10.2 ounce size (290 grams) Study date December 14, 2007	to be assigned	Bushwacker Backpack & Supply Co., Inc.	OWN		
TOXICITY						
870.2400	Primary Eye Irritation Study in Rabbits	46136702	Bushwacker Backpack & Supply Co., Inc.	OWN		
870.2500	Primary Skin Irritation Study in Rabbits	46136703	Bushwacker Backpack & Supply Co., Inc.	OWN		
Signature	2-11-		Name and Title Cristina Griffin Agent for Bu and Supply Co., Inc.	shwacker Backpack	Date 12/20/07	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

October 24, 2007 E-Mail

Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904

Attention: Ms. Cristina Griffin

Subject: Counter Assault Bear Deterrent

EPA Reg. No. 55541-2

Your amended application of December 20, 2006

Your resubmission of February 27, 2007

Our letter of July 2, 2007 Our meeting of July 19, 2007

Purpose The purpose of this submission, under section 3 of the Federal Insecticide,

Fungicide, and Rodenticide Act (FIFRA), is to replace your existing Confidential Statements of Formula (CSF), November 24, 2003, and March 16, 2006, with a new CSF, dated December 20, 2006, including a new inert ingredient not found in any currently registered product.

Review A. New Non-Food Inert

1. Initial Review

Based on our initial review communicated in our July 2, 2007, letter, we were not able to approve your new inert because of the toxicity profile of the new, non-food inert.

For that initial assessment, we did not consider the amount of minimal exposure to the environment from a bear repellent. Normally, for new, non-food inerts, we must consider exposure from all potential uses.

Review continued

2. July 19, 2007, Meeting

At this meeting we discussed additional information that you had provided the Agency and agreed to reconsider our initial decision <u>not</u> to permit the inclusion of the new, non-food inert in your bear repellent.

3. Reconsideration of New, Non-Food Inert in a Bear Repellent

After further consider, we have determined that we will, in fact, allow the use of your proposed new, non-food inert in your bear repellent product. We will only allow this inert to be used in bear repellent products, not for any other use site, including food.

B. Spray Pattern Data

- Because the initial spray pattern data were unacceptable, you will need to repeat those data for each can size for the new formula.
- 2. Because of the additional time needed to develop and to review these data, we will need to re-negotiate the PRIA due date, which expires on November 12, 2007. How much time would you need to conduct these studies? If you can send us the new data within one (1) month, we would propose to extend the PRIA due date until February 12, 2008. Would this new date be acceptable to you? If so, send us an E-Mail stating that you would project sending in the new spray pattern data by December 12, 2007, and would request an extension of the PRIA Due Date of three (3) months, or February 12, 2008.

Ouestions

If you have questions about this letter, please contact me at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock, dan@epa.gov (by E-Mail).

Sincerely yours,

Daniel B. Peacock, Biologist Insecticide-Rodenticide Branch

Damiel B. Rearch

Registration Division (7504C)

Dan Peacock, Flash Drive, 2gb, P:\Documents\Word, WP, Excel, etc\Capsaicin\55541-2\New Non-food Inert\55541-2, new CSF, new inert, 10-24-2007.doc



December 20, 2007

Document Processing Desk (RESUB)
Office of Pesticide Programs (7504P)
Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive, Room S-4900
Arlington VA 22202

Attn: John Hebert, PM 7/ Dan Peacock, Insecticide-Rodenticide Branch

Re: Resubmission of spray pattern study as per your request and letter of October 24,

2007

Product: Counter Assault Bear Deterrent

EPA Reg. No.: 55541-2

Company: Bushwacker Backpack and Supply Company, DBA Counter Assault

Dear Mr. Hebert/Mr. Peacock:

On behalf of Bushwacker Backpack and Supply Company, DBA Counter Assault, we are submitting a revised spray pattern study as requested in your letter of October 24, 2007. The study was conducted similarly to the study Counter Assault conducted and EPA approved July 8, 2004.

Enclosures:

- EPA form 8570-1
- Certification with Respect to Citation of Data form
- Data matrix
- Volume 1 of 1, Counter Assault Bear Deterrent EPA Reg. No. 55541-2 Spray Pattern 8.1 ounce (230 grams) and 10.2 ounce (290 gram) size dated 12/14/07
- EPA letter dated October 24, 2007

If you have any questions regarding this submission, please call me at (301) 680-7971 or email cgriffin@delta-ac.com.

Sincerely,

Cristina Griffin

Agent for Counter Assault

cc: Pride Johnson, Counter Assault



December 20, 2007

Document Processing Desk (RESUB)
Office of Pesticide Programs (7504P)
Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive, Room S-4900
Arlington VA 22202

Attn: John Hebert, PM 7/ Dan Peacock, Insecticide Rodenticide Branch

Re: Resubmission of spray pattern study as per your request and letter of

October 24, 2007

Product: Counter Assault Bear Deterrent

EPA Reg. No.: 55541-2

Company: Bushwacker Backpack and Supply Company,

DBA Counter Assault

Data Transmittal Letter Pursuant to FIFRA Section 3

Dear Mr. Hebert/Mr. Peacock:

On behalf of Bushwacker Backpack and Supply Company, DBA Counter Assault, I am submitting three copies of the following study as requested for the product Counter Assault Bear Deterrent, EPA Reg. No. 55541-2.

 Volume 1 of 1 Counter Assault Bear Deterrent EPA Reg. No. 55541-2 Spray Pattern 8.1 ounce (230 grams) and 10.2 ounce (290 gram) size, December 14, 2007

MRID # 47308201

If you have any questions regarding this submission, please call me at (301) 680-7971 or email cgriffin@delta-ac.com.

Sincerely,

Cristina Griffin

Agent for Counter Assault

cc: Pride Johnson, Counter Assault



United States

Environmental Protection Agency Washington, DC 20460

☐ Registration
☐ Amendment
X Other

OPP Identifier Number RE-SUBMISSION

		Application for P	Pesticide - Section I				
1. Company/Product Number 5554	1-2		2. EPA Product Manager John Hebert /Dan	Peacock	3. Propose	d Classification	
4. Company/Product (Name) Bush Company, DBA Counter / Deterrent			РМ #7				
5. Name and Address of Applicant (In Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Drive, S Silver Spring, MD 20904 Check if this is a new address			6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No Product Name				
		Sect	tion - II				
☐ Amendment - Explain below X Resubmission in response to Agency letter dated October 24, 2007 ☐ Notification - Explain below.			☐ Final printed labels in res☐ "Me Too" Application.☐ Other - explain below.	sponse to Agen	cy letter dated		
Explanation: Use additional page(s) Resubmission of spray patte			of October 24, 2007.				
		Sect	ion - III		j		
1. Material this Product will be Pac	kaged In:						
Child Resistant Packaging Yes* No	Unit Packag ☐ Yes ☐ No	ing	Water Soluble Packaging ☐ Yes ☐ No		2. Type of Container Metal Plastic Glass		
* Certification must be submitted.	ff "Yes," Unit Packag	e wgt. No. per container	If "Yes," Unit Package wgt. No. per container		☐ Paper ☐ Other (Specify)		
Location of Net Contents Informatio Label	n	4. Size(s) of Retail Contain	iner 5. Location of Label Direction On Label On Labeling accompan				
6. Manner In Which Label Is Affixed to	Product	☐ Lithograph ☐ Paper glued ☐ Stenciled	□ Other				
		Secti	ion - IV				
1. Contact Point (Complete items direct	tly below for identil	fication of individual to be con	tacted, if necessary, to process	s this application	n.)		
Name Cristina Griffin			Agent for Counter Assault		Telephone No. (Include Area Code) 301-680-7971		
I certify that the statements I have may of knowingly false or misleading stater			rue, accurate and complete. I a	acknowledge (h	at any kind	6. Dute Application Received	
2. Signapore Pettua	8-11		3. Title Agent for Counte	er Assault		(Stamped)	
4. Typed Name Cristina Griffin	717		5. Date December 20, 2007				



B. Spray Pattern Data

- The new spray pattern data are acceptable, provided you submit proposed, revised labeling to reflect that
 - a. for the 230g can, the label states "The canister empties in approximately 7.1 seconds." and
 - b. for the 290g can, the label states "The canister empties in approximately 8.2 seconds."

Note: In the future, we will re-review the spray pattern data of all bear spray products to determine if those values are minimum or average values and require everyone to adhere to the same standard by a certain date. We will also indicate the precision allowed on the label.

2. In addition, if your new formula replaces the previous two (2) formulas, you may propose in your revised label to increase the range of the 230g can to "32 feet" and increase the range of the 290g can to 36 feet.

Questions If you have questions about this letter, please contact me at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock,dan@epa.gov (by E-Mail).

Sincerely yours,

Daniel B. Peacock, Biologist Insecticide-Rodenticide Branch Registration Division (7504C)

Dan Peacock, Flash Drive, 2gb, P:\Documents\Word, WP, Excel, etc\Capsaicin\55541-2\New Non-food Inert\55541-2, new CSF, new inert, 2-11-2008.doc

IRB EFFICACY REVIEW

DP Number(s)

348429

IN: 1/16/08 OUT: 2/6/08

PRODUCT NO.: 55541-2

DATE RECEIVED BY OPP: 12/21/07

DATE OF SUBMISSION: 12/20/07

DATE SUBMISSION ACCEPTED: 1/6/08

TYPE OF PRODUCT: Animal-attack Repellent

DATA MRID or ACCESSION NOS.: 473082-01

PRODUCT MANAGER NO.: 07

PRODUCT NAME: COUNTER ASSAULT BEAR DETERRENT

COMPANY NAME: Bushwacker Backpack & Supply Co., Inc. ("dba COUNTER ASSAULT")

SUBMISSION PURPOSE: Document spray time and pattern for a proposed alternate

formulation

CHEMICAL & FORMULATION: 2.0% Capsaicin and related capsaicinoids aerosol

Efficacy Review: COUNTER ASSAULT BEAR DETERRENT, 55541-2

Bushwacker Backpack & Supply Co., Inc. (a.k.a. "dba COUNTER ASSAULT")

Kalispel, MT 59901

200.0 INTRODUCTION

THIS REVIEW DISCUSSES CONFIDENTIAL BUSINESS INFORMATION (CBI). DO NOT DISCLOSE CBI TO UNAUTHORIZED THIRD PARTIES OR TO ANYONE LACKING APPROPRIATE CLEARANCES. THIS REVIEW DISCUSSES AN INERT INGREDIENT THAT IS NOT MANUFACTURED BY THE REGISTRANT OR THE REGISTRANT'S AGENT. CONSEQUENTLY, THOSE ENTITIES MAY BE UNAUTHORIZED THIRD PARTIES WITH RESPECT TO SOME INFORMATION DISCUSSED HERE.

200.1 Uses

55541-2 is a 2.00% Capsaicin (1.04%) and Other Capsaicinoids (0.96%) aerosol Federally registered for use at unspecified sites

only to deter bears which are attacking or appear likely to attack humans.

200.2 Background Information

See efficacy reviews of 1/5/98, 1/26/99, 4/22/99, 8/6/99, 7/14/00, 9/5/00, 9/21/00, 12/28/00, 12/7/01, 7/2/01, 6/29/04, 8/1/05, and 6/5/07, along with other information in the two-volume registration jacket for 55541-2. See also the enforcement case reviews of 9/9/05 for FY05-VIII-005 and 1/17/08 for FY08-VIII-001. Note discussions of claims made in labeling and advertising for this product and other bear pepper sprays. See especially discussions of previously submitted spray pattern studies in efficacy reviews of 1/5/98, 6/29/04, and 6/5/07. 55541-2 was registered on 5/12/98 as the first U.S. registration for Capsaicin-containing bear repellent. Such products were sold illegally in the U.S. prior to that time. The current labeling for 55541-2 was "ACCEPTED with COMMENTS" on 11/22/04.

This review primarily addresses the report of a spray pattern study that Bushwacker's agent, Christina Griffin of Delta Analytical Corp., Silver Spring, MD, submitted on 12/20/07. That submission was a follow-up to several others that were related to an alternate formulation proposed for 55541-2. The efficacy review of 6/5/07 addressed various elements of the original application for that formulation amendment. The items considered in that review included a Confidential Statement of Formula (CSF), another spray pattern study, and various other documents. The amendment has a negotiated extended PRIA due-date of 2/11/08.

For this review, I was sent Griffin's letter of 12/20/07, the spray pattern report, and several odd items related to this product's recent regulatory history. Since receiving the review package, I have received several e-mails about it. Some of these items are discussed, where appropriate, in this review.

According to Griffin's letter of 12/20/06 which accompanied the original amendment application, Bushwacker/COUNTER ASSAULT wanted Agency approval of an alternative formulation using

That substance had not been cleared as an inert ingredient for use in pesticides in the U.S. when Bushwacker, via Griffin, applied to have it included in an alternate formulation for 55541-2. In her letter of 12/20/06, Griffin indicated that the registrant wanted to be able to formulate this product without and "volatile organic compounds (VOCs)" in it.

The initial proposal to include in a formulation for 55541-2 generated a great deal of discussion within OPP and various communications involving OPP, the registrant, and Griffin. Adding the new inert ingredient initially was rejected due to concerns about toxicity, but a subsequent finding was that

The Inert Ingredient Assessment Branch (IIAB) has approved the use of as a [sic] inert ingredient that can only be used in pesticide products applied as bear repellents. This chemical is not approved for use in pesticides applied to any other site, including food.¹

That conclusion was conveyed to Griffin via IRB's letter of 10/24/07, and a way was paved toward accepting the pending alternate formulation ("#2", CSF of 12/20/06) or a similar CSF claiming inclusion of

The spray pattern report (MRID# 470668-01) submitted on 2/27/07 was not accepted. See efficacy review of 6/5/08 for a full discussion of that document, which also is summarized in this review.

Bear pepper sprays are to be used protect humans in what may literally be life-or-death situations. Successful use of a bear pepper spray typically would spare the human and the bear from significant long-term adverse health consequences. The nature of the spray pattern delivered by a container of bear pepper spray is integral to the product's utility, as are the distance over which an effective spray cloud travels and the duration (in seconds) of availability of a useful spray pattern.

Claims as to spray distance and effective spraying time also have been featured in promotional battles between registrants of bear pepper sprays. As is chronicled in the registration jacket for this product, Bushwacker/COUNTER ASSAULT has been a protagonist in some battles and a target in others. Such battles have been fairly frequent and often have involved EPA, informally and formally, as with enforcement cases FY05-VIII-005 and FY08-VIII-001.

In its most immediately relevant part, §2(q) of FIFRA defines "MISBRANDED" as

¹ "<u>MEMORANDUM</u>" of 10/17/07 from Deborah McCall, Acting Branch Chief, Inert Ingredient Assessment Branch (IIAB), RD/OPP, to Dan Peacock, Insecticide-Rodenticide Branch (IRB), RD/OPP.

(1) A pesticide is misbranded if--

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;...

In <u>40 CFR</u> §156.10(a)(5), the Code of Federal Regulations provides examples of types of statements which categorically are regarded as "false or misleading". These categories (quoted immediately below) are indicated in <u>40 CFR</u> §156.10(a)(5)(I) through (x).

- (i) A false or misleading statement concerning the composition of the product;
- (ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
- (iii) A false or misleading statement concerning the value of the product for purposes other than as a pesticide or device;
 - (iv) A false or misleading comparison with other pesticides or devices;
- (v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;
- (vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;
- (vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;
- (viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations.
- (ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans or pets" with or without such a qualifying phrase as "when used as directed"; and
- (x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:
 - (A) "Contains all natural ingredients";
 - (B) "Among the least toxic chemicals known"
 - (C) "Pollution approved".

Of the 10 categories of "false or misleading" statements listed under 40 CFR §156.10(a)(5), items "(ii)" and "(iv)", effectiveness and inter-product comparisons, are most relevant to the results of spray pattern tests.

201.0 DATA SUMMARY

201.1 Formulations

A CSF dated "3/16/06" was stamped "APPROVED 9/13/06 SM", signed by "Paul J Mastradone", and hand-marked "last approved SF 3-16-2006". That CSF is for an

"Alternative Formulation". The "Basic" CSF for 55541-2 seems to be the one dated 11/24/03, which IRB accepted on 7/8/04. Accepting that CSF increased the nominal concentration of Capsaicin and related capsaicinoids in 55541-2 from 1.73% (CSF of 3/4/98) to 2.0%. The CSFs of 11/24/03 and 3/16/06 both appear to be current. They describe formulations that are very similar but differ with respect to suppliers of Oleoresin Capsicum – the source of active ingredients – and have compensatory differences in the concentrations of the inert ingredients claimed. The source listed on the CSF of 3/16/06 apparently is slightly "hotter" than the source claimed on the CSF of 11/24/03.



201.2 Efficacy Data

The new spray pattern test report is cited and discussed below.

Johnson, P. (2007) Counter Assault Bear Deterrent: EPA Reg. No. 55541-2 spray pattern study 8.1 ounce (230g) and 10.2 ounce size (290g). Unpublished report, Bushwacker Backpack and Supply Co., Inc. DBA Counter Assault, Kalispel, MT, 7 pp.

MRID# 473082-01

This report is dated "December 21, 2007". Thus, it was completed after the decision was made to clear as an inert ingredient limited to use in bear repellents. The report states that actual testing was done "between November 12 and November 29, 2007".

The testing was performed in a "plastic spray booth" that was "erected in Counter Assault's warehouse". The indoor temperature reportedly was 70°F, but the "heater" was turned off and all doors were closed "to eliminate any wind". The booth reportedly was 14 feet wide (with expansion to 16 feet possible) and 14 feet high on its left side and 16 feet high on its right side "(conforming to the slope of the warehouse)". The booth was created by draping "clear plastic" over a frame. The plastic covering reportedly stretched to 38 feet, but

The spray tester could move back an additional 12 feet, for a possible total spraying distance of 50 feet.

If there were indoor air circulation, it is possible that the booth's covering and/or the air space within it could have been affected. However, doors to the warehouse were opened for "1-1.15 hours" after each sample was tested; and the heater subsequently was run for "30-45 minutes" to return the warehouse temperature to 70°F.

All testing reportedly involved the formula, as described in the

Confidential Statement of Formula, Alternate Formulation #2, dated 12/20/06, using Oleoresin Capsicum Lot # A18849.

Five cans per size were tested simultaneously for spray duration and spray pattern.

Spray duration reportedly was timed via stopwatch.

The time was measured for product spayed at which a strong and visual spray was being emitted from the can. The time was stopped when the spray ceased to be emitted in a strong force.

Personnel weighed cans before and after spray duration testing to calculate the amount of contents removed during the useful spraying period. After the second weighing, "the residual pressure was released and the can re-weighed" so as to determine the amount of "product remaining in the can after timing had ceased."

Pride Johnson and his assistants (other "employees") examined "white cardboard targets" as well as the "plastic walls around each target" to assess "spray coverage". Via telephone on 2/5/08, Johnson told me that targets were located on the back wall, on the floor, and on the side walls, near the back wall ("in the corners"). Targets were replaced between tests, and the "plastic walls" were "wiped with a clean white paper towel." Impingements of spray on surfaces were

verified by visual inspection of the white cardboard targets and also by wiping the plastic walls at approximately a 2-foot diameter circle with the paper towel. Tasting of the spray residue ensured that it had the pungent taste of Oleoresin Capsicum (OC).

Five more cans of each size were tested to assess the number of spray bursts of approximately 1-sec that the cans could deliver.

For the 230-g container, spray durations of 7.17, 7.34, 6.91, 7.01, and 7.08 seconds were reported. These results are consistent with a container evacuation claim of "approximately 7 seconds". Johnson reports a mean time of 7.1 seconds. Amounts of material evacuated during the spray duration tests ranged from 229.7 to 232.3 g, with the mean amount being 231.2 g. The residual weights subsequently evacuated ranged from 0.6 to 1.1 g, averaging 0.8 g. Thus, all containers held at least 230 g of product.

The width of the spray pattern was reported to be 14 feet for the first unit tested and 15 feet for the 4 others. As the booth was set to a 14-foot width for the first unit, the width of the pattern reported for it may have been an artifact of the initial setup. Visual assessments of spray impingements were rated as "Very Noticeable" or "Extremely Noticeable" for both the "Target" and the "Wipe Samples". "Moderately Noticeable" was the third rating possible. Taste sampling of targets led to ratings of "Very Pungent" to "Extremely Pungent". "Moderately Noticeable" also was possible.

The spray distance was reported to be 32 feet for 3 units and 34 feet for the other 2. These distance figures reportedly were determined from inspecting targets and side walls and may or may not have represented the distance between the sprayer and the back wall of the spray booth. Assuming them to be accurate, these results are consistent with a spray distance claim of 32 feet for the formulation tested.

The tests for numbers of "approximately 1-second" spray bursts yield results of 7, 7, 8, 7, and 6 bursts for the 5 cans that were tested. Johnson reports that these data produce a mean of 7.20 bursts. What the extra 0.2 of an "approximately 1-second" burst might mean to a prospective user of the product is not clear. Interestingly, Johnson reported on another sort of fraction, namely the duration of spraying time left after the last "approximately 1-second" burst was fired. These times ranged from 0.02 to 0.89 sec, with the longest residual firing time being for the can that had delivered 6 bursts of "approximately 1-second". The 2 shortest residual times were for 7-burst cans. The results of this test are consistent with a claim of "approximately 7 one-second bursts" or a firmer claim of "6 or more firing bursts of approximately one second". Any label claim concerning number of "approximately one-second bursts" would have to reflect the results of the 55541-2 formulation that performed worst in that area.

For the 290-g container, spray durations of 8.18, 8.36, 8.22, 8.44, and 8.19 seconds were reported. These results are consistent with a container evacuation claim of "approximately 8 seconds". Johnson reports a mean time of 8.28 seconds. Amounts of material evacuated during the spray duration tests ranged from 289.7 to 299.3 g, with the mean amount being 291.4 g. The residual weights subsequently evacuated ranged from 0.8 to 1.4 g, averaging 1.1 g. Therefore, all containers reportedly exceeded 290 g in net contents.

The width of the spray pattern was reported to be 14 feet for the first unit tested and 16 feet for the 4 others. The booth was set to a 14-foot width for the first unit. Therefore, the width reported for its pattern may have been determined by the initial setup. Visual assessments of spray impingements were rated as "Very Noticeable" or "Extremely Noticeable" for both the "Target" and the "Wipe Samples". Taste sampling of targets led to "Extremely Pungent" ratings for all cans.

The spray distance was reported to be 36 feet for one unit, 40 feet for another, 42 feet for 2 cans, and 44 feet for one. Those results are consistent with a spray distance claim of 36 feet.

The tests for numbers of "approximately 1-second" spray bursts yield results of 8, 8, 9, 8, and 8 bursts for the 5 canisters tested. Johnson reports a mean of 8.20 bursts.

Johnson reports that the durations of spraying time left after the last "approximately 1-second" burst was fired ranged from 0.03 to 0.69 sec, with the longest residual firing time being for a can that had delivered 8 bursts of "approximately 1-second" and the shortest being for the 9-burst can. The results of this test are consistent with a claim of "approximately 8 one-second bursts" or a claim of "8 or more firing bursts of approximately one second".

The current label for the 230-g container for 55541-2 bears a spray distance claim of "up to 30 feet (9 meters)" and a useful spray duration of "approximately 7.2 seconds". As the label claims must cover all formulations that might be in the container, accepting the CSF of 12/20/06 or a similar formulation document would leave the spray distance claim unaltered but would require shortening the duration claim. The new claim would be "approximately 7 seconds" or "approximately 7.1 seconds", if including tenths of seconds is believed to be consistent with the word "approximately" and to not be misleading in any particular.

When the 10.2-oz (290-g) container was accepted for 55541-2 (label "ACCEPTED with COMMENTS" on 7/8/04), the registrant was instructed to shorten the spray duration claim for it from "approximately 9.2 seconds" to 9.0 seconds (IRB's letter of 7/8/04). Through a former agent, the registrant petitioned to have the 9.2-seconds claim. accepted (and also a 7.2-second claim instead of 7 seconds for the 230-g can). IRB apparently was influenced to add the tenths to the duration claims. On 11/22/04, IRB accepted a label for the 230-q without comment on the claim of "approximately 7.2" seconds" that appeared on it. No copy of a stamped label for the 290-q can appears in the jacket for 55541-2, and the OPPIN label image does not show such a label, either, and lacks the other elements of labeling that appear from the jacket to have been accepted for 55541-2. IRB's letter of 11/22/04 mentions having accepted "can labels (8.1 oz and 10.2 oz sizes)" provided that certain conditions unrelated to claims of spray duration be met. The bundle of items related to IRB's letter of 11/22/04 in the jacket for 55541-2 includes a clamshell insert label that bears a 9.2-second claim for the 290-q container. Thus, it appears that IRB accepted a spray duration of "approximately 9.2" seconds" for the 290-g can.

None of the evacuation times that Johnson (2007) reports for 290-g containers of the pending alternate formulation reached 9.2 seconds. As noted above, those times ranged from 8.18 to 8.44 seconds, averaging 8.28 seconds. So that the label for the 290-g can covers the performance of the quickest of the 3 formulations that it might contain, the spray duration claim for that size must be reduced either to "approximately 8 seconds" or, if tenths claims are to be continued to be allowed, "approximately 8.2 seconds". Given the potentially life-or-death circumstances of this product's intended use, rounding the mean up to 8.3 seconds does not seem like a good idea. All of the spray-duration results obtained with the 290-g can round to at least 8.2 seconds; and 3 of the 5 results round to 8.2 seconds. Spray times for the other 2 cans round to 8.4 seconds. Therefore, 8.2 seconds seems to be more representative of what one could expect from the container than 8.3 seconds.

The results reported for this study can only be taken at face value. Shortly after receiving the efficacy review package, I examined its contents and noted the absence of

raw data. I raised the matter with Peacock, and he informed Griffin via e-mail on 1/16/08 of the "needs to send in raw data supporting the values in the submitted volume." Griffin replied via an e-mail message of 1/17/08. In relevant part, her response is quoted below.

Yesterday you requested that we provide the raw data for the study. I spoke with Pride Johnson, who conducted the study and wrote the report. He has never kept the raw data for any of the reports submitted to EPA and EPA has never requested it. After testing, the results were calculated and transferred to the computer; the sheets on which the time and distance were written were discarded, as they were often soiled and did not appear to be useful.

Mr. Johnson was careful in conducting the study and is confident of the results he obtained. Mr. Johnson is willing to sign a certification that the report truthfully and accurately represents the results of the spray pattern study he conducted. Please let me know if you want him to send you such a certification.

No certification would help in this situation. The numbers reported either are accurate or they are not. A person who would fudge data would likely certify to the veracity of made-up figures. These statements reflect an assessment of how things go in the world and are not meant to imply that Johnson fudged any data. From speaking with him concerning this trial and the ones conducted earlier in the 21st century, it seems clear enough that he ran spray pattern tests. The results reported are consistent with other data that I have seen for trials with other containers and formulations. However, not all of the reports of those trials included raw data, either.

We commonly receive raw data with efficacy submissions and commonly request such information when the initial submission lacks raw data. The circumstances under which the first bear pepper sprays were registered involved a degree of urgency and a willingness on our part to accept spray pattern reports at face value in order to move things along. (For a product that no longer is registered, the spray pattern data submitted might indeed have been fabricated.) In cases in which spray pattern trials were video-taped, I had the opportunity to view the tests myself and to check the times and examine the spray patterns. In effect, taped evidence functionally took the place of raw data.

At 40 CFR §160.195, EPA's "GOOD LABORATORY PRACTICE STANDARDS" (GLPs) require retention of raw data for the duration of "any research or marketing permit to which the study is relevant" or, if longer, for "5 years following the date on which the results of the study are submitted to the EPA" to support "an application for a research or marketing permit." Among other things, a pesticide registration qualifies as a marketing permit. The report for the Johnson (2007) study states that it was not a GLP study. Indeed, it was not.

Aside from stating what was tested, Johnson (2007) does not document the formulation of the test material.

The results reported by Johnson (2007) for the 230-g canister showed greater consistency in evacuation times and greater spray distances than were indicated in the first spray-pattern report that was submitted for the second alternate formulation proposed for 55541-2. The report of the earlier study is cited and briefly summarized below. Much of the information on it was imported and abridged from the efficacy review of 6/5/07.

Griffin, C. and Johnson, P. (2007) Counter Assault Bear Deterrent EPA Reg. No. 55541-2 spray pattern. Unpublished report, Bushwacker Backpack and Supply Co., Inc. DBA Counter Assault, Kalispel, MT, and Delta Analytical Corporation, Inc., Silver Spring, MD, 5 pp. plus 4-page "CONFIDENTIAL APPENDIX".

MRID# 470668-01

This trial reportedly was run outdoors on 9/11/06. The test site was "a small clearing in a wooded area". The testing reportedly was performed (or began) at 9:30 AM on a day "with virtually no wind at approximately 75°F." Cans of the "Basic" product (presumably that described by the CSF of 11/24/03) and the "AF" (alternate formulation) "were sprayed and the spray distance and pattern were visually monitored." The 2 versions of the product were alternated in testing. Spray "distances of 26 to 34 feet were measured in 2 foot increments."

As no raw data sheets accompanied the Griffin and Johnson (2007) report, it was not possible to determine whether the time of testing and the ambient temperature were recorded at any phase of the trials. As the trials could not have been completed instantaneously, a start time and a finish time should have been recorded at the very least. The ambient temperature probably changed somewhat over the course of time taken to complete the testing. Wind speed and direction should have been measured right before each individual canister was tested.

Spray distances ranging from 26 to 34 feet were reported for the 12 "AF of 230 grams" units tested. Each of these results was compared to the 30-foot distance listed on the "Basic Label (230g)", with 6 test canisters reportedly exceeding that distance, 4 equaling it, 2 falling short of it (by 2 and 4 feet). The "average" spray distance for the "AF of 230 Grams" was reported to be "31 feet", slightly farther than the "30 feet" claimed for the "Basic Label (230g)".

Spray durations ranging from 5.97 to 9.07 seconds were reported for the 12 "AF of 230 grams" test units. The reported "Average AF (230g)" spray time was "7.7 seconds", slightly more than the "7.2 seconds" reported for the "Basic Label (230g)".

Griffin and Johnson (2007) reported no tests of the larger (290-g) Counter Assault container with the "AF" in it. Instead, they estimated what the spray distances and durations for such a container might have been.

Since the spray distance is almost identical and the spray duration is within 0.5 seconds (acceptable variation in operating stopwatch), a mathematical correlation for the AF 290 can is:

AF 290/230 (7.68)= 9.7 seconds 290/230(31)= 39 feet Basic Label = 9.2 seconds = 32 feet

When Johnson (2007) tested 290-g containers, he obtained a mean evacuation time of 8.28 seconds and spray distances of 36 to 44 feet. Among other things, it appears that the conditions of testing employed by Johnson (2007) were superior to those reported by Griffin and Johnson (2007). It also is clear enough that extrapolation from the results of one container size to project likely results for another size can yield inaccurate results. All sizes must be tested.

The shortest reported spray time for the "AF of 230 Grams" was 5.97 seconds, which rounds to 6 seconds. As the spray-duration part of the Griffin and Johnson (2007) may have been valid, one might consider that 6 seconds should be the spray duration claim permitted for 55541-2 if and when the "Alternate Formulation #2" described by the CSF of 12/20/06 (or similar document) is accepted. That result was the lowest of 12 units tested. Johnson (2007) did not obtain any times below 6.91 seconds for the 5 units that he tested. Therefore, it seems possible that the 5.97-second time was not well taken. If, on the other hand, that time was well taken and reflects what one in 15-20 of the 230-g cans produces, it should be considered to be the time claimed on the label for 55541-2. At this time, I am inclined to substitute the results of Johnson (2007) for those of Griffin and Johnson (2007). In the case of spray distance, it seems more likely that the procedures used by Griffin and Johnson would have underestimated distances. Johnson's (2007) indoor testing with confirmatory tasting should have been more accurate.

202.0 CONCLUSIONS

1. The report of spray patterns and spray durations by Johnson (2007, MRID No. 473082-01) show average evacuation times of useful spray of 7.1 seconds for the five 230-g containers tested and 8.28 seconds for five 290-g containers. These results mean that the evacuation times claimed on the labels for these containers must be shortened if the formulation described by the Confidential Statement of Formula (CSF) dated "12/20/06" is accepted for 55541-2. Label claims must be consistent with the quickest evacuation performance obtained with any of the alternate formulations that are used in the product.

The claim of effective spray duration for the 230-g (8.1-oz) container should read:

The canister empties in approximately 7 seconds.

As the average spray duration for the 230-g container reported by Johnson (2007) to contain the formulation described by the CSF of 12/20/06 was 7.1 seconds, the following claim also could be accepted:

The canister empties in approximately 7.1 seconds.

However, the slowest reported time for those containers was under 7 seconds.

One of the 12 containers of reportedly the same formulation that Griffin and Johnson (2007, MRID No. 470668-01) tested had an evacuation time of under 6 seconds. The timing results reported for that trial were highly variable and may have resulted from problems with the conduct of that study. However, the variable results might also reflect a quality control issue. To rule out the latter possibility, record the results of quality control testing of batches of "Alternate Formulation #2" and compile them into a report, attaching the relevant raw data to that report. Submit that report within 18 months of the acceptance of the CSF of 12/20/06 or, if that document must be replaced before the new inert ingredient may be used in 55541-01, acceptance of the new CSF that describes essentially the same formulation. We will review those data and determine whether adjustment of the spray duration claim is needed for the 230-g container.

The spray-time and spray-pattern data that Johnson (2007) reports for 10.2-oz (290-g) cans are the first results supplied to us for the formulation described by the CSF of 12/20/06 in that container. The spray times reported ranged from 8.18 seconds to 8.44 seconds, averaging 8.28 seconds. For 3 of the containers, the times reported round to 8.2 seconds. The times reported for tested 290-g containers were well below the average time that was extrapolated by Griffin and Johnson (2007) from their results for the 230-g container. As the results for tested 290-g containers of the new alternate formulation were well below the 9.2-second spray duration claim currently on the label for 290-g canister, that label must be altered so as to reflect the times that the new alternate formulation was shown to deliver. All other elements of labeling where such claims appear also must be altered to reflect the new spray-duration times.

The claim of effective spray duration for the 290-g (10.2-oz) container should read:

The canister empties in approximately 8 seconds.

As all spray-duration times for the 290-g container reported by Johnson (2007) exceeded 8 seconds and 3 of the 5 units yielded times that round to 8.2 seconds, the following claim also could be accepted:

The canister empties in approximately 8.2 seconds.

2. The effective spray distances that Johnson (2007) reports for the 230-g and 290-g cans tested exceed those claimed on the current labels for those containers. However, the distance claims on those labels – 30 feet for the 230-g can and 32 feet for the 290-g can – must remain as they are so that the claims are consistent with the shortest distance results reported for all of the formulations that may be used in 55541-2.

- 3. The numbers of "approximately 1-second" bursts of spray that reportedly were delivered in Johnson's (2007) trials were 6-8 for the 230-g cans and 8-9 for the 290-g can. These results are consistent with claims of 6 bursts for the 230-g can and 8 bursts for the larger one. As claims regarding bursts of "approximately 1-second" do not appear on current accepted labeling for 55541-2, no changes to those are needed to reflect the results of one-second-burst trials. Label changes are needed, to reflect the shorter spraying times reported for both sizes.
- 4. No raw data were supplied to substantiate the values reported by Johnson (2007). Consequently, his data could be reviewed only at face value. The raw data reportedly were thrown out once the numbers were entered into a computer document. Note that retention of raw data is addressed by requirements in 40 CFR §160.195 and that submission of raw data typically is required for efficacy data pertaining to vertebrate pesticides.

William W. Jacobs Biologist Insecticide-Rodenticide Branch February 6, 2008



Date: 16-Jan-2008 Page 1 of 3

Decision #: 376199

Parent DP#:

DP #: (348429)

PRIA

* Registration Information * * *

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55541-2 - COUNTER AS	SSAULT BEAR	DETERRENT		_
55541 - BUSHWACKER BAC	KPACK & SUPPLY	∞.		4
RM 07 - John Hebert - (703) 3	08-6249 Room# PY	1 S-7227		
Daniel Peacock DPEACOCK				
	Calculated Due D	Date: 12-Nov-2007	Edited	Due Date:
Product Registration - Section	3			
(R34) NON-FAST-TRACK (IN	CLUDES CHANGE	S TO PRECAUTIO	NARY LABEL STATEME	<u>r</u>
070701, Capsaicin(2%)				
* * * Da	ta Package I	nformation	***	
	_			20.20
Yes No	Date S	Sent: 16-Jan-2008	_	Due Back:
070701, Capsaicin				
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	55541-2 - COUNTER AS 55541 - BUSHWACKER BAC RM 07 - John Hebert - (703) 3 Daniel Peacock DPEACOCK Product Registration - Section (R34) NON-FAST-TRACK (IN- 070701, Capsaicin(2%) * * * Da Yes No 070701, Capsaicin	55541-2 - COUNTER ASSAULT BEAR 55541 - BUSHWACKER BACKPACK & SUPPLY RM 07 - John Hebert - (703) 308-6249 Room# PY Daniel Peacock DPEACOCK Calculated Due D Product Registration - Section 3 (R34) NON-FAST-TRACK (INCLUDES CHANGE 070701, Capsaicin(2%) *** Data Package I Yes No Date S 070701, Capsaicin Yes No Label Included: Yes	Calculated Due Date: 12-Nov-2007 Product Registration - Section 3 (R34) NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIO 070701, Capsaicin(2%) * * * Data Package Information Yes No Date Sent: 16-Jan-2008 070701, Capsaicin Yes No Label Included: Yes No Package Information Date In Date Out	55541-2 - COUNTER ASSAULT BEAR DETERRENT 55541 - BUSHWACKER BACKPACK & SUPPLY CO. RM 07 - John Hebert - (703) 308-6249 Room# PY1 S-7227 Daniel PeacockDPEACOCK Calculated Due Date: 12-Nov-2007 Edited Product Registration - Section 3 (R34) NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL STATEME 070701, Capsaicin(2%) *** Data Package Information *** Yes No Date Sent: 16-Jan-2008 070701, Capsaicin Yes No Label Included: Yes No Parent DP#: Date In Date Out B Last Possible Science

Here is the done spray pattern data for this product (55541-2), which had to be redone because they did not follow the standard protocol. They had to redo the data originally because they changed over 1/2 of their formula. That included a new-non-food inert that was rejected at first, then accepted, based on the low exposure.

Enclosures:

- 1. app form
- 2. cover letter
- 3. data
- 4. background information

if you have any questions, please contact me.





DP#: (348429)		* * * Additio	Page		cision * * *		sion#: (376199)
DP#		Division/Branch	Date Sent	Date Due	Instructions?	CSF	label
339786	RD/IRB		10-May-2007	11-Jun-2007	Yes No	Yes No	Yes No
339786	RD / IRB		10-May-2007	11-Jun-2007	Yes No	Yes No	Yes No

DP#: (348429)

* * * Studies Sent for Review * * *

Decision#: (376199)

Guideline

MRID MRID Status 47308201

Citation Reference

Johnson, P. (2007) Counter Assault Bear Deterrent: Spray Pattern Study: 8.1 Ounce (230g) and 10.2 Ounce Size (290g). Unpublished study prepared by Bushwacker Backpack & Supply Co. 7 p.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

October 24, 2007 E-Mail

Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904

Attention: Ms. Cristina Griffin

Subject: Counter Assault Bear Deterrent

EPA Reg. No. 55541-2

Your amended application of December 20, 2006

Your resubmission of February 27, 2007

Our letter of July 2, 2007 Our meeting of July 19, 2007

Purpose The purpose of this submission, under section 3 of the Federal Insecticide,

Fungicide, and Rodenticide Act (FIFRA), is to replace your existing Confidential Statements of Formula (CSF), November 24, 2003, and March 16, 2006, with a new CSF, dated December 20, 2006, including a new inert ingredient not found in any currently registered product.

Review A. New Non-Food Inert

1. Initial Review

Based on our initial review communicated in our July 2, 2007, letter, we were not able to approve your new inert because of the toxicity profile of the new, non-food inert

For that initial assessment, we did not consider the amount of minimal exposure to the environment from a bear repellent. Normally, for new, non-food inerts, we must consider exposure from all potential uses.



continued

2. July 19, 2007, Meeting

At this meeting we discussed additional information that you had provided the Agency and agreed to reconsider our initial decision <u>not</u> to permit the inclusion of the new, non-food inert in your bear repellent.

3. Reconsideration of New, Non-Food Inert in a Bear Repellent

After further consider, we have determined that we will, in fact, allow the use of your proposed new, non-food inert in your bear repellent product. We will only allow this inert to be used in bear repellent products, not for any other use site, including food.

B. Spray Pattern Data

- Because the initial spray pattern data were unacceptable, you will need to repeat those data for each can size for the new formula.
- 2. Because of the additional time needed to develop and to review these data, we will need to re-negotiate the PRIA due date, which expires on November 12, 2007. How much time would you need to conduct these studies? If you can send us the new data within one (1) month, we would propose to extend the PRIA due date until February 12, 2008. Would this new date be acceptable to you? If so, send us an E-Mail stating that you would project sending in the new spray pattern data by December 12, 2007, and would request an extension of the PRIA Due Date of three (3) months, or February 12, 2008.

Questions

If you have questions about this letter, please contact me at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock, dan@epa.gov (by E-Mail).

Sincerely yours,

Daniel B. Peacock, Biologist Insecticide-Rodenticide Branch

Damiel B. Pearal

Registration Division (7504C)

Dan Peacock, Flash Drive, 2gb, P:\Documents\Word, WP, Excel, etc\Capsaicin\55541-2\New Non-food Inert\55541-2, new CSF, new inert, 10-24-2007.doc





December 20, 2007

Document Processing Desk (RESUB)
Office of Pesticide Programs (7504P)
Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive, Room S 4900
Arlington VA 22202

Attn: John Hebert, PM 7/ Dan Peacock, Insecticide-Rodenticide Branch

Re: Resubmission of spray pattern study as per your request and letter of October 24,

2007

Product: Counter Assault Bear Deterrent

EPA Reg. No.: 55541-2

Company: Bushwacker Backpack and Supply Company, DBA Counter Assault

Dear Mr. Hebert/Mr. Peacock:

On behalf of Bushwacker Backpack and Supply Company, DBA Counter Assault, we are submitting a revised spray pattern study as requested in your letter of October 24, 2007. The study was conducted similarly to the study Counter Assault conducted and EPA approved July 8, 2004.

Enclosures:

- EPA form 8570-1
- Certification with Respect to Citation of Data form
- Data matrix
- Volume 1 of 1, Counter Assault Bear Deterrent EPA Reg. No. 55541-2 Spray Pattern 8.1 ounce (230 grams) and 10.2 ounce (290 gram) size dated 12/14/07
- EPA letter dated October 24, 2007

If you have any questions regarding this submission, please call me at (301) 680 7971 or email cgriffin@delta-ac.com.

Sincerely,

Cristina Griffin

Agent for Counter Assault

cc: Pride Johnson, Counter Assault





December 20, 2007

Document Processing Desk (RESUB)
Office of Pesticide Programs (7504P)
Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive, Room S 4900
Arlington VA 22202

Attn: John Hebert, PM 7/ Dan Peacock, Insecticide-Rodenticide Branch

Re: Resubmission of spray pattern study as per your request and letter of

October 24, 2007

Product:

Counter Assault Bear Deterrent

EPA Reg. No.:

55541-2

Company:

Bushwacker Backpack and Supply Company,

DBA Counter Assault

Data Transmittal Letter Pursuant to FIFRA Section 3

Dear Mr. Hebert/Mr. Peacock:

On behalf of Bushwacker Backpack and Supply Company, DBA Counter Assault, I am submitting three copies of the following study as requested for the product Counter Assault Bear Deterrent, EPA Reg. No. 55541 2.

 Volume 1 of 1 Counter Assault Bear Deterrent EPA Reg. No. 55541-2 Spray Pattern 8.1 ounce (230 grams) and 10.2 ounce (290 gram) size, December 14, 2007

MRID # 47308201

If you have any questions regarding this submission, please call me at (301) 680-7971 or email cgriffin@delta-ac.com.

Sincerely,

Cristina Griffin

Agent for Counter Assault

cc: Pride Johnson, Counter Assault



Decision#: 376199 Registration#: 55541-2 Petition #:

Fee Category: R-34 PRIA Decision Time Frame: 4 months

Submitted by: Dan Peacock Branch: IRB Date: 11-7-2007

Company: Counter Assault (Agent: Delta Analytical Corp)

Original Due Date: 7-11-2007 Proposed New Due Date: 2-11-2007 (Monday)

Previous Negotiated Due Dates: 11-12-2007 (Monday)

Is the "Fix" in-house? No If not, date "Fix" expected: 12-11-2007

Issue (describe in detail):

- Co requested a revised CSF to comply with California's request to phase out a VOC carrier.
- EPA's Office of Air & Radiation has listed the replacement carrier as acceptable.
- · However, proposed carrier is a new, non-food inert, which has chronic effects to 5 mg/kg/da.
- The product, a Bear Deterrent, an aerosol, might result in 1 exposure in a lifetime. However, our current policy does allow us to approve new, non-food inerts, based on exposure.
- Our Inerts Integration Assessment Branch (IIAB) has said that they do not have the staff to review non-non-food inerts by use pattern. They had consulted with OGC on this issue of approving new, non-food inerts based on exposure prior to completing their initial review.
- The amendment also involved spray pattern efficacy data that will have to be repeated.

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

- Prior to the first extension of the PRIA Due Date from July 11 to Nov 12, 2007, the co and EPA agreed to a 120 day extension to allow time for:
 - o OPP to consider exposure in the approval of new, non-food inerts;
 - OPP to consult with EPA's Office of Air and Radiation, if needed;
 - o OPP to consult with OGC, if needed;
 - Registrant to repeat efficacy data; and
 - o OPP to review new efficacy data.



Interactions with Company - continued

- On July 19, 2007, representatives of IRB and IIAB met with the company agent to discuss their petition to the Agency to review this new, non-food inert.
- After IIAB reviewed the company's petition, IIAB decides that the new, non-food use could be used in pesticide products, but <u>only in bear deterrent products</u>.
- We communicated this decision to the company verbally on Sep 13 and in writing on October 24, 2007.
- Having resolved that issue, on October 11, the company sought clarification on the efficacy
 testing (spray pattern data) that the company must conduct because it changed 54% of its
 formulas. We addressed those questions on November 6, 2007.
- On Nov 6, 2007, after additional conversations with the registrant's agent, Ms. Griffin sent me an E-Mail, copy attached, agreeing to an 120 day extension, February 11, 2008.

Rationale for Proposed Due Date:

- · Allow company one (1) month to redo the efficacy test and
- · Allow EPA three (3) months to review the efficacy data.

Other Comments:

Note: At the time that EPA received this amendment under PRIA I, there were no codes for new, non-food inerts. However, under PRIA II, there are codes for such actions so we would not have this problem in the future of not receiving money for an action that needs considerable resources.

Approve:	Disapprove:
If disapproved, action to be taken:	
OD or DOD Signature:	Date:

Dan Peacock, Flash Drive 2gb, F:\Documents\Word, WP, Excel, etc\Capsaicin\55541-Z\New Non-food Inert\2nd Negotiated Due Date, 2-11-2008 req, 11-6-2007.doc



United States

Environmental Protection Agency Washington, DC 20460

☐ Registration ☐ Amendment **OPP Identifier Number** RE-SUBMISSION

· ·				X Otner		SOBIMISSION
		Application for P	esticide - Section I			
Company/Product Number 5554	1-2		2. EPA Product Manager John Hebert /Dan I	Peacock	3. Proposed Classification ☐ None ☐ Restricted	
					- I Note Restricted	
5. Name and Address of Applicant (Include ZIP Code) Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904 Check if this is a new address			Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No Product Name			g to:
		Sect	ion - II			
☐ Amendment - Explain below X Resubmission in response to Agend ☐ Notification Explain below.	cy letter dated Octo	ober 24, 2007	☐ Final printed labels in res☐ "Me Too" Application.☐ Other explain below.	sponse to Agen	cy letter dated	
Explanation: Use additional page(s) Resubmission of spray patt		er EPA letter request o				
		Sect	ion - III		1	
1. Material this Product will be Page	kaged In:					
Child-Resistant Packaging ☐ Yes* ☐ No	Unit Packaging ☐ Yes ☐ No		Water Soluble Packaging ☐ Yes ☐ No		2. Type of Container Metal Plastic Glass	
* Certification must be submitted.	ff "Yes," Unit Packag	e wgt. No. per container	If "Yes," Unit Package wgt. No. p	No. per container ☐ Other (Specify)		er
Location of Net Contents Information Label	n	4. Size(s) of Retail Contain	ner	5. Location of Label Direction On Label On Labeling accompanying product		
6. Manner In Which Label Is Affixed to	Product	☐ Lithograph ☐ Paper glued ☐ Stenciled	Other			
		Secti	ion - IV			
Contact Point (Complete items dire	ctly below for identi	fication of individual to be con	tacted, if necessary, to process	s this application	n.)	
Name Cristina Griffin		Agent for Counte	Telephone No. (Include Area Co			
I certify that the statements I have ma of knowingly false or misleading state	ide on this form and	Certific	rue, accurate and complete. I a	icknowledge th	at any tind	6. Date Application Received
2. Signal re	8-11		3. Title Agent for Counter Assault		(Stamped)	
4. Typed Name Cristina Griffin		5. Date December 20, 2007				

ENFORC	CEMENT CASE REVIE	W	I	PRODUCT REGISTRATION STATUS	
ECR Log No. FY08-VIII-001			Registered		
			Product L	abei	
BRANDNAME: COUNTER ASSAULT® BEAR DETERRENT		COMPANY NAME: COUNTER ASSAULT ADDRESS: 120 INDUSTRIAL COURT KALISPEL, MT 59901			
			Basic Registrat	ion Status	
	XI REGISTERED	DATE ACCEPTED: 5/12/98 EPA REGISTRATION NO.: 55541-2	a very effort to the party of the united	E: COUNTER ASSAULT S: 120 INDUSTRIAL COURT KALISPEL, MT 59901	
	☐ I INREGISTERED	NO APPLICATION	NC		
			FILE SYMBOL:		
		CANCELED/SUSP ENDED	DATE:	EXISTING STOCK DEADLINE: DISTRIBUTOR DEADLINE: USER DEADLINE:	
			REGISTRANT	REQUESTED	
			NONPAYMENT	OF MAINTENANCE FEES	
			CANCELLATIO	A / STISPENSION ORDER OF.	
			OTHER.		
		☐ EXEMPTED			
	· · · · · · · · · · · · · · · · · · ·		Distributor Regist	ration Status	
SUPPLEM	ENTAL REGISTRATION	☐ YES	X NO DISTRIE	ADDRESS:	
DATE OF S	SUPPLEMENTAL REGIST	RATION:	PRODU	CT NAME:	
		Pe	rtinent Registrati	on Information	
	w. Similar issues also ha		n direct correspond	05, which addressed issues similar to those addressed ence with the registrant. There are no distributor pro	
			Pesticide / Dev	ce Status	
STHIS A PES	STICIDE?		. IS	THIS A DEVICE?	
YES		O PESTICIDAL CLAIMS O PESTICIDAL EFFECT		Ives DNO	

Pest Control Claims and Other Factors That Identify the Product as a Pesticide or Device

According to its accepted label, this product is to be used "only to deter bears which are attacking or appear likely to attack humans." In that context, bears are considered to be pests.

ENFORCEMENT CASE REVIEW

II. CONCERNS

ECR Log No. FY08-VIII-001

Product Labeling

Brand name: COUNTER ASSAULT® BEAR DETERRENT

Company name: Counter Assault

ADDRESS: 120 INDUSTRIAL COURT

KALISPEL, MT 59901

Review

This enforcement case review (ECR) pertains primarily to two tables which list and compare certain aerosol spray products that are registered under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to deter bears from attacking humans. These products all list Capsalcin and related capsalcinoids as the active ingredient mixture.

The Items routed for review include:

- a "TRANSMITTAL" memorandum dated "12/18/07" from the Toxics and Pesticides Enforcement Division (TPED) of EPA's Office of Regulatory Enforcement (ORE) to the Registration Division (RD) of EPA's Office of Pesticide Programs (OPP);
- a string of e-mail communications from 12/14-12/17/07, originating with Tim Osag of EPA's Region 8 office, Denver, CO, and involving Mary McDonnell of TPED/ORE as primary addressee and respondent;
- an "ECR REQUEST FORM" dated "12/14/2007";
- a table captioned "EPA REGISTRANTS OF BEAR PEPPER SPRAY PRODUCTS IN ORDER OF REGISTRATION DATE"; and
- part of a table captioned "BEAR PEPPER SPRAY COMPARISON CHART".

The BEAR PEPPER SPRAY COMPARISON CHART (called "CHART #2" in the appendix to the ECR REQUEST FORM) apparently was printed on 11/29/07 from the web address "http://www.counterassault.com/Bear_Deterrent/body_counter_assault_bear_deterrent.html". The "EPA REGISTRANTS OF BEAR PEPPER SPRAY PRODUCTS IN ORDER OF REGISTRATION DATE*" table shows the handwritten notation "http://www.counterassault.com/Bear Spray Comparison Chart".

The TRANSMITTAL memorandum includes the hand-written instructions and comments quoted immediately below.

NOTE: The request has been revised. The new request is – Do the charts bear claims that were not accepted in connection with the product's registration? If so, please identify them and indicate whether they would be acceptable if they were submitted.

The ECR REQUEST FORM poses the question

Can we regulate misleading statements in advertising that is not referenced on the product label and which does not appear to fall under the scope of 40 CFR 162.22. [sic].

That question appears to be what the TRANSMITTAL memorandum has "revised"

The ECR REQUEST FORM also includes an "Attachment. Summary of Findings: Counter Assault Advertising" which indicates how the tables came to the attention of EPA Region 8 and also discusses their content. UDAP industries, inc., Bozeman, MT, provided Region 8 with the tables. UDAP is the registrant of the product "UDAP PEPPER POWER." BEAR DETERRENT, EPA Reg. No. 72007-1, which is one of the products listed in the 2 tables. The ECR REQUEST FORM refers to "two charts Region 8 reviewed in October 2004" and notes differences among those Items and the tables included in the current ECR. The "charts Region 8 reviewed in October 2004" may have been similar to the tables addressed in ECR FY05-Viii-005 which were found at points of sale of 55541-2 and other bear pepper spray products.

On 1/16/08, I visited the http://www.counterassault.com/Bear_Deterrent/body_counter_assault_bear_deterrent.html site and found a table captioned "BEAR PEPPER SPRAY COMPARISON CHART" that corresponds in content (but not in margins) with the table bearing the same name that is include in the enforcement case file. This table lists the 4 registered bear pepper spray products as the last 4 column headings in a 6-columns-X-8-rows matrix. The first column is captioned

Environmental Protection Agency Requirements and Guidelines suggested by bear biologists, wildlife specialists, individuals who have been involved in confrontation with bears and field testing.

This caption seems inaccurate for the row headings that appear in descending order down the first column: "Date EPA Registered", "Manufactured by", "Maximum Net Weight", "% Capsaicin & Other Capsaicinoids", "Minimum Range (Reason), "Time of Continuous Spray (Why?)", and "Meet Guidelines?".

The second column is captioned "Guidelines (established by bear biologists & wildlife specialists)". Some of the cells under that heading lack entries. Entries do appear as "7.9 ounces" and the metric equivalent "225 grams" for "Minimum Net Weight", as "1-2%" for "% Capsalcin & Other Capsalcinoids", as "25 feet" for "Minimum Range (Reason)", and as "6 seconds" for "Time of Continuous Spray (Why?)". Opposite the row headings under the column headings for the various registered products are entries that are presented as being accurate for them.

For the Counter Assault product 55541-2, all entries are in boldface; and some are presented in larger type than are the corresponding row entries for the other 3 products. The "Date EPA Registered" entry for "Counter Assault" is accurate ("May 12, 1998") but is embellished by the addition of "(The First!)". Although 55541-2 was the first to be registered among the products listed on the BEAR PEPPER SPRAY COMPARISON CHART and was the first bear pepper spray to be registered in the U.S., it was not the first bear deterrent spray to be registered here. Claiming it to be "The First" is not completely accurate. Such a claim might be interpreted further as meaning that "The First" product is somehow better than the others, which perhaps would be perceived as imitators. The row headed by "Manufactured by" lists "Counter Assault" for the Counter Assault product. That information appears to be accurate. Company No. "55541" was assigned to Bushwacker Backpack & Supply Co., of the same Kalispel, MT, address as Counter Assault, which is the company name now used on labels for 55541-2. The Bushwacker name appeared on the product's label in 1998 when it was registered. The information presented in the column for 55541-2 regarding container contents, active ingredient concentration, and time of continuous spray all accurately represent text on the labels accepted for the 8.1-oz canister and/or the 10.2-oz canister. The spray distance claim of "30 feet" for the 8.1-oz container is consistent with its label, but the table claims "35 feet" rather than the claim of "32 feet" that appears on the accepted label for the 10.2-oz container. Opposite the row heading "Meet Guidelines?", the column entry for Counter Assault is "YES", presented in bold red type that is about twice as large as the "NO" entries in the same row that come under the column headings for the 3 competitors' products.

The information presented on the BEAR PEPPER SPRAY COMPARISON CHART in the column for "Guard Alaska" (EPA Reg. No. 71545-1, McNell River Enterprises, inc., of Anchorage, AK, and/or Canton, OH) is accurate and consistent with the product's accepted label with respect to the figures entered for initial registration date, container size, spray distance, and container evacuation time ("Time of Continuous Spray"). However the entry of "15-20 ft." for spray distance ("Minimum Range") is embellished by the addition of "(Does NOT meet Guidelines)". Apparently for that reason, Guard Alaska was given a "NO" entry for "Meets Guidelines?". The entry of "1.3%" for concentration of active ingredients is a figure to which the label claim (1.34%) for 71545-1 rounds. For "Manufactured by" the table indicates "Contract Filier" for Guard Alaska. The registrant's establishment is not the one identified on the accepted label for 71545-1.

The information presented on the BEAR PEPPER SPRAY COMPARISON CHART in the column for "Pepper Power" (EPA Reg. No. 72007-1) is accurate and consistent with accepted product labels with respect to the numerical entries for initial registration date, container sizes, active ingredient concentration, spray distance, and container evacuation times. The entries of "4 sec" for the 7.9-oz container and "5.4" sec for the 9.2-oz container are followed by "(Does NOT meet Guidelines)", and Pepper Power was given a "NO" entry for "Meets Guidelines?". For "Manufactured by" the table indicates "Contract Filler" for Pepper Power. The registrant's establishment number (72007) is listed on the label for 72007-1, but filling containers might not be regarded by UDAP as the final act in producing the product. The 72007-1 product originally was registered (as 71920-1) to an entity that was its producer. UDAP originally was a distributor for the 71920-1 registration, which was transferred to UDAP effective 3/6/03.

The information presented on the BEAR PEPPER SPRAY COMPARISON CHART in the column for "Frontiersman Bear Peppermace" (EPA Reg. No. 72265-1, Security Equipment Corporation, Fenton, MO) is accurate for the numerical entries for initial registration date, manufacturer, container sizes, active ingredient concentration, spray distance, and container evacuation times. The entries of "5 sec" for both the 7.9-oz and 9.2-oz containers are followed by "(Does NOT meet Guidelines)", and Frontiersman Bear Peppermace was given a "NO" entry for "Meets Guidelines?". For "Manufactured by" the table indicates "Contract Filier" for Pepper Power. An establishment number for the registrant is listed on the label for 72265-1, and that entity seems to produce that product.

The most problematic aspects of the BEAR PEPPER SPRAY COMPARISON CHART are the comparisons that it makes among the registered bear pepper spray products and the inferences that the reader is left to draw. EPA has set minimum net contents for bear pepper spray products (at 7.9 oz = 225 g) and has indicated that such products containing 1-2% of Capsalcin and related capsalcinoids could be registered as bear deterrents in the U.S. EPA also requires that spray distances and spray evacuation times be determined for bear pepper sprays, for each container size used, and that the summary figures from those tests be indicated on labels. However, EPA has registered and continues to register all of the bear pepper sprays listed in on the BEAR PEPPER SPRAY COMPARISON CHART. Thus, EPA has not determined that any of the results for which that table presents "Does NOT Meet Guidelines" disqualified the product at issue from being registered. The spray tests for some of the products were videotaped. EPA reviewed those tapes and verified the times reported. Some videotaped information showing use of pepper spray products against bears also was submitted. It was observed that the animals turned tall after spraying events that were a fraction of a second in duration, although the conditions of testing did not always mimic the charging of an aggressive bear.

The differences among product stated of amplied in the BEAR PEPPER SPRAY COMPARISON chart are emphasized and embellished at the http://www.counterassault.com/Bear_Deterrent/body_counter_assault_bear_deterrent.html site by additional text that appears under headings "Why is a Minimum of Six Seconds important?" and "Why is a minimum of 25 feet important" below the table and in text that precedes it (e.g., "Hottest Available", "Only University Tested Bear Pepper Spray 1980-1986", "Original Developer & Manufacturer – incorporated 1986", "Innovator of The Fogger Technology", "T EPA registered – Established industry standards 1997", "Recipient of the Grizzly Bear Stewardship Award 1998", and "Meets or Exceeds Bear Biologist Recommendations"). All of the reference activities that occurred before 5/12/98 preceded the date when 55541-2 was registered. Counter Assault and some other bear pepper spray products were marketed illegally prior to that date.

No claims of comparative effectiveness have been accepted on labels or labeling for 55541-2, nor would they be likely to be. For comparative claims not to qualify as being false or misleading, their presentations would have to provide the complete contexts under which relevant tests were performed and present a completely unbiased account of their results so that the reader would be free to draw informed conclusions. The amount of text needed to accomplish those ends likely would take up too much space to fit on labels or labeling, and the Agency's review of the proposed information still might uncover misleading text and/or falsehoods. EPA has set 7.9 g as the minimum net contents amount for containers of bear pepper spray products and requires that the spray distance and container evacuation times are to be indicated on labels for each size of container. Beyond those findings, EPA has made no judgments as to whether the differences among products in those parameters would make one better than any of the others. While having a longer total spraying time might seem to offer something of an advantage, delivering a larger volume of material per unit time might offer a different sort of advantage against an attacking bear. As mentioned above, actual spray events in videotaped usages of this type of product have been less than one second. Therefore, it would seem that the times listed for all container sizes of all registered products would allow for more than one use of the product before the container's useful contents were evacuated. Spray distance might prove to be an especially important parameter in protecting humans from attacking bears, but insufficient information has been presented to EPA to support inferences that a product with a spray distance of 15-20 feet would not protect a person under circumstances when a product with a spray distance of 30 feet or more would.

Whether the minima for spray duration and spray distance that the BEAR PEPPER SPRAY COMPARISON CHART attributes to "bear biologists & wildlife specialists" are appropriate goes beyond the scope of efficacy data submitted to EPA for registrations of bear pepper sprays. How and why such specifications came to be is not completely clear. Their development has been portrayed as having been independent of Bushwacker Backpack & Supply, Co./Counter Assault, and that may have been the case.

The labeling of pesticides and devices registered in the U.S. is governed by Federal insecticide, Fungicide, and Rodenticide Act(FiFRA), as amended, and regulations issued thereto and compiled in Title 40 of the U.S. <u>Code of Federal Regulations</u> (40 CFR). Making false or misleading comparisons with other pesticides on labeling is categorically prohibited in 40 CFR §156.10(a)(5)(iv).

Section 2(p)(2) of FIFRA defines "Labeling" as meaning

all labels and other written, printed, or graphic matter-

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and the Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

Neither the BEAR PEPPER SPRAY COMPARISON CHART nor the EPA REGISTRANTS OF BEAR PEPPER SPRAY PRODUCTS IN ORDER OF REGISTRATION DATE* table (discussed below) is referenced by the accepted labels and labeling for 55541-2. No web address appears on those documents. Therefore, those tables and other items wed-linked to it appear not to qualify as labeling. Rather, they are advertising materials.

On 1/16/08, I obtained access to the EPA REGISTRANTS OF BEAR PEPPER SPRAY PRODUCTS IN ORDER OF REGISTRATION DATE* table (CHART #1) from the http://www.counterassault.com/Bear_Deterrent/body_counter_assault_bear_deterrent.html site by clicking on the "Comparison Chart" button found there. That table presents much of the same sort of information that appears in the BEAR PEPPER SPRAY COMPARISON chart, but there are some differences. Information on all products is presented in the same type size and typeface throughout CHART #1. A row heading "Megaphone Shaped Cloud" (which "establishes an expanding area of protection") appears on the CHART #1 table, but the "Yes" entries in that row for all products mean that it draws no distinctions among them.

For each product, row subheadings of "Company Name:", "Manufacturer:", and "Location:" have been inserted on CHART #1. The registrants' names and locations are entered for "Counter Assault" and "Frontlersman", whereas "Guard Alaska" is reported to be manufactured by "Washington Labs" in "Ohio" and "Pepper Power" is reported to be manufactured by "independent fillers" whose "Locations vary". For Guard Alaska, the information presented in CHART #1 is inconsistent with Establishment No. (36213-MD-002) that appears on the product's most recently accepted label (stamped on 2/2/00), but it might be accurate for more recent production. Those who prepared "CHART #1", might have included "Location:" information to imply that only Counter Assault is made in "grizzly country" or to influence Montana residents to buy a product made in their State.

The row in CHART #1 that pertains to EPA registration information is captioned "EPA Registration (Must be Registered by Act of Congress" with a separate line for "Date of Registration". The row entries for registration numbers and dates are accurate.

For "Minimum Net Weight*" 7.9 ounces Up et 225 grams", accurate and heading-consistent mormation is provided for all products. The asterisks in this heading refer the reader to the words "Established by EPA", which is an accurate representation. This row heading is embellished by the following sentence: "Less than this amount may not be sufficient to determore than one bear or more than one charge or encounter." That text is reasonably consistent with EPA's rationale in setting the minimum amount of product per container.

Also referenced with the words "Established by EPA", is the CHART #1 row heading "Capsaicin & Related Capsaicinoids** 1 – 2 percent". That representation is accurate. This row heading has the following explanatory text added to it: "Determined by testing and field experience. The effectiveness is reasonably equivalent." Those characterizations are consistent with the process that EPA went through in setting the range of active-ingredient strength. The information upon which it was based consisted of summary articles of field experiences in the U.S. and Canada, some reports of experimental work, and some videotaped encounters.

The information provided in CHART #1 regarding "Minimum Range – 25 feet" ("Minimum sufficient distance to give the bear time to divert its charge and avoid contact") is consistent with the distances indicated on accepted labels for all listed container sizes for all 4 accepted products, including "32 ft" for the 10.2-oz size of Counter Assault.

The information provided in CHART #1 for "Minimum Time of Continuous Spray – 6 seconds" is consistent with the times indicated on accepted labels for all accepted container sizes for all 4 accepted products. The cell box for this row heading also contains the text quoted below.

Minimum spray time for more than one bear or more than one charge/encounter, with compensation for wind, rain, temperature, and/or the hike out.

As noted above, EPA has found that the registered bear pepper sprays are appropriate for use as they currently are constituted. The minimum for spray time, which excludes all registered bear pepper spray products except Counter Assault, has been represented to EPA as having originated with people who might be characterized as "bear biologists & wildlife specialists". EPA has not seen information sufficient to support 6 seconds as a minimum spray time but did consider limits on effective spray time in its decision not to allow containers of less than 7.9 oz of product to be labeled as bear pepper sprays.

Consistent with the BEAR PEPPER SPRAY COMPARISON CHART, the EPA REGISTRANTS OF BEAR PEPPER SPRAY PRODUCTS IN ORDER OF REGISTRATION DATE* table has "Yes" entries only in the cells for Counter Assault containers in the bottom row captioned "Meets All Wildlife Specialists & Bear Biologist Suggested Guldelines?". The reasons for "No" entries for containers of the other registered products are not highlighted in CHART #1 but appear to be the same as those that are highlighted in CHART #2. It is here that the absence of the information regarding the recently accepted 13.4-oz container for Pepper Power, mentioned in the attachment to the "ECR REQUEST FORM", makes a difference. The label for the 13.4-oz container of 72007-1 is labeled with an evacuation time of "approximately 7 seconds" and "range of up to 35 feet". Thus, Pepper Power in that container would seem to merit a "Yes" entry for "Meets All Wildlife Specialists & Bear Biologist Suggested Guldelines?" As the 13.4-oz container for Pepper Power was accepted on 10/18/07, its existence might not yet be known to the designers of the web pages for Counter Assault. When it appears in the marketplace, if not sooner, Counter Assault will become aware of the largest accepted size for Pepper Power containers.

Although the information in CHART #1 is more subdued than that in CHART #2, the comparisons among products implied by CHART #1 are much the same as those presented with more "fire" in CHART #1. As noted above, brief comparisons among registered products are inherently false or misleading; and providing sufficient context to permit accurate comparisons on pesticide labels essentially is unfeasible.

40 CFR §168.22 addresses "Advertising of unregistered pesticides, unregistered uses of pesticides and FIFRA section 24(c) registrations." §168.22(a) states that

(a) FIFRA sections 12(a)(1) (A) and (B) make it unlawful for any person to "offer for sale" any pesticide if it is unregistered, or if claims made for it as part of its distribution or sale differ substantially from any claim made for it as part of the statement required in connection with its registration under FIFRA section 3. EPA interprets these provisions as extending to advertisements in any advertising medium to which pesticide users or the general public have access.

The comparative representations in CHART #1 and CHART #2, especially those which state or imply an advantage or superiority for Counter Assault (55541-2), differ from those accepted for that product.

REVIEWER NAME/ SIGNATURE:	SUPERVISOR NAME/SIGNATURE	DATE:	
William W. Jacobs	Meredith F. Laws		



Dan Peacock/DC/USEPA/US

1/08/2007 07:34 AM

To John Hebert/DC/USEPA/US@EPA

CC

bcc

Subject 55541-2, Counter Assault Bear Deterrent, Request to Extend PRIA Due Date to Feb 11, 2008

John,

 I will shortly be putting in your chair the package to extend the PRIA Due Date until Feb 11, 2008 for 55541-2 for an Amendment for this product.

The package includes an original and four copies of the 1) request and 2) company's concurrence

with the proposed new PRIA date.

As the current PRIA Due Date, Nov 12, 2007, falls on a Federal Holiday, we need to forward this
request this morning to insure that we have a timely sign-off.

I am including electronic versions of the 1) request and 2) buck slip in cese you need to edit them.



2nd Negotiated Due Date, 2-11-2008 req, 11-6-2007.doc



Re-Neg PRIA Date, Sign-off.BuckSlip, 11-8-2007.doc

Let me know if you need anything from me.

I will be working at home tomorrow, if anything comes up.

Thank You,

Daniel B. Peacock, Biologist Tel: 703-305-5407 Fax: 703-305-6920 E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

R	ROUTING AND TRANSMITTAL SLIP Date Nove			
): (Name, office symbol nency/Post)	ol, room number, building,		
1.	John Hebert			
2.	Meredith Laws			
3.	Lois Rossi			
4.	Marty Monell			
5.				
6.)			
X	Action	File	Note and Return	
X	Approval	For Clearance	Per Conversatio	
	As Requested	For Correction	Prepare Rep	
	Circulate	For Your Information	See Me	
	Comment	Investigate	Signature	
	Coordination	Justify		

RENEGOTIATION OF PRIA DATE:

Attached for your consideration is the following document:

Counter Assault Bear Deterrent, EPA Reg. No. 55541-2.

PROM: (Name, org. symbol, Agency/Post) Dan Peacock, Biologist	CubeNo 7262, PY1
Insecticide-Rodenticide Branch	
	Phone No. 703-305-5407

Dan Peacock, Flash Drive, 2gb, P:\Documents\Word, WP, Excel, etc\CapsalcIn\55541-2\New Non-food Inert\Re-Neg PRIA Date, SIgn-off.BuckSlip, 11-8-2007.doc

Recommendation of Division Directors Negotiated Due Dates

Decision#: 376199	Registration#:	55541-2	Petition #:
Fee Category: R-34		PRIA Decision	n Time Frame: 4 months
Submitted by: Dan Peacock		Branch: IR	B Date: 11-8-200
Company: Counter Ass	ault (Agent: Delta Ai	nalytical Corp)	
Original Due Date: 7-11-2007 Pr		Proposed New Du	ne Date: 2-11-2007

Issue (describe in detail):

Is the "Fix" in-house? No

Co requested a revised CSF to comply with California's request to phase out a VOC carrier.

If not, date "Fix" expected: 12-11-2007

- EPA's Office of Air & Radiation has listed the replacement carrier as acceptable.
- However, proposed carrier is a new, non-food inert, which has chronic effects to 5 mg/kg/da.
- The product, Counter Assault Bear Deterrent Bear Deterrent, an aerosol, might result in 1
 exposure in a lifetime for an individual user. However, our current policy (as of July 2007)
 did not allow us to approve new, non-food inerts, based on exposure, no matter how small.
- Our Inerts Integration Assessment Branch (IIAB) had said that they do not have the staff to review non-non-food inerts by use pattern. They had consulted with OGC on this issue of approving new, non-food inerts based on exposure prior to completing their initial review.
- The amendment also involved spray pattern efficacy data that will have to be repeated.

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

- Prior to the first extension of the PRIA Due Date from July 11 to Nov 12, 2007, the co and EPA agreed to a 120 day extension to allow time for:
 - OPP to consider <u>exposure</u> in the approval of new, non-food inerts;
 - o OPP to consult with EPA's Office of Air and Radiation, if needed;
 - o OPP to consult with OGC, if needed;
 - Registrant to repeat efficacy data; and
 - o OPP to review new efficacy data.

Interactions with Company - continued

- On July 19, 2007, representatives of IRB and IIAB met with the company agent to discuss their petition to the Agency to review this new, non-food inert.
- After IIAB reviewed the company's petition, IIAB decides that the new, non-food inert could be used in pesticide products, but <u>only in bear deterrent products</u>.
- We communicated this decision to the company verbally on Sep 13 and in writing on October 24, 2007.
- Having resolved that issue, on October 11, the company sought clarification on the efficacy
 testing (spray pattern data) that the company must conduct because it changed 54% of its
 formulas. We addressed those questions on November 6, 2007.
- On Nov 8, 2007, after additional conversations with the registrant's agent, the company's
 agent sent me an E-Mail, copy attached, agreeing to a 90 day extension, February 11, 2008.

Rationale for Proposed Due Date:

- · Allow company one (1) month to redo the efficacy test and
- Allow EPA three (2) months to review the efficacy data.

Other Comments:

Note: At the time that EPA received this amendment under PRIA I, there were no codes for new, non-food inerts. However, under PRIA II, there are codes for such actions.

Approve:	Disapprove:	
If disapproved, action to be tak	en:	

Dan Peacock, Flash Drive 2gb, F:\Documents\Word, WP, Excel, etc\Capsaicin\55541-2\New Non-food Inert\2nd Negotiated Due Date, 2-11-2008 req, 11-6-2007.doc



Dan Peacock/DC/USEPA/US 11/07/2007 08:11 AM

To "Pride Johnson" <pri>pride@counterassault.com>

cc "Cristina Griffin" <cgriffin@delta-ac.com>, John Hebert/DC/USEPA/US@EPA, Bill Jacobs/DC/USEPA/US@EPA

bcc

Subject Re: Fw: Counter Assault Labeling Issues, EPA Reg. No. 55541-2

Dear Mr. Johnson,

- Thank you for pointing out that additional information. I agree with your comments about correspondence.
- The correct values for your product are 7 and 9 seconds.
- In the one E-Mail, I stated that:

We do not believe that the average user could tell whether the product discharged in 7.2 or 7 seconds and in 9.2 or 9 seconds. However, since we allowed the decimal point for UDAP, we will allow it for Counter Assault.

- Apparently, I did not fully appreciate at the time that the difference between the values for Counter Assault represented both a difference in precision and average/minimum values.
- I cannot tell from the text if the values allowed for UDAP represented average or minimum values.
 They should have been minimum.
- We will review data supporting the label values for all bear deterrent products to determine if those
 values are minimum or average values & require everyone to change to minimum by a certain date, if
 they are currently using average values. We will also indicate the precision allowed on the label.
- In that way we will have treated all bear deterrent products similarly.
- [In the past, I believe that the data have been so consistent, there has been little difference between
 minimum and average values. However, potentially, the values could be quite difference. Allowing
 average values from tests where individual values vary greatly could lead to misleading and
 life-threatening misinformation on the label.]

Daniel B. Peacock, Biologist Tel: 703-305-5407 Fax: 703-305-6920 E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

"Pride Johnson" <pride@counterassault.com>



"Pride Johnson"
<pride@counterassault.com>

11/06/2007 02:59 PM

To Dan Peacock/DC/USEPA/US@EPA

cc "Cristina Griffin" <cgriffin@delta-ac.com>, John Hebert/DC/USEPA/US@EPA

Subject Fw: Counter Assault Labeling Issues, EPA Reg. No. 55541-2



Dan.

Received your official email to Cristina Griffin of November 6, 2007 regarding resubmission of 10 11-07 & telephone conversation 10 05-07.

I took offense to your comment of Item 2, 2nd paragraph stating "we conditioned our acceptance of your labeling in July 2004 ... to include changing the discharge time from 9.2 to 9 seconds ... and from 7.2 to 7 seconds In a later approval (November 2004), you included the incorect values, ... Below are two emails between you and Elizabeth Brown of ChemReg. In your email of August 5, 2004 to Elizabeth Brown, Item #2 stating "However, since we allowed the decimal point for UDAP, we will allow it for Counter Assault". Counter Assault did not use an incorrect value, your email response approved the decimal values.

This is one of the problems with not having official correspondence from the EPA on EPA letterhead. In the future we request that all correspondence relating to label approvals be submitted on EPA letterhead, whether via mail or email.

Pride Johnson Counter Assault

-- Original Message -----

From: "Kirsten Johnson" <kirsten@counterassault.com>

To: "pride johnson" <pride@counterassault.com>

Sent: Tuesday, November 06, 2007 12:19 PM

Subject: Fw: Counter Assault Labeling Issues, EPA Reg. No. 55541 2

>> ----Original Message---->> From: Elizabeth Brown >> Sent: Friday, August 06, 2004 8:29 AM >> To: 'Peacock.Dan@epamail.epa.gov' >> Cc: Hebert.John@epamail.epa.gov >> Subject: RE: Counter Assault Labeling Issues, EPA Reg. No. 55541-2 >> >> >> Dan: >> On behalf of our client, Counter Assault, I want to thank both you and >> John for taking the time to talk with me and to allow the opportunity to >> address the issues on an informal basis to ensure good understanding by >> both the registrant and EPA. This also will help improve the process for >> any agreed upon revisions. >> >> I just wanted to recap our discussion about your email: >> >> For item 1 (clamshell packaging): you identified that because this >> product is associated with preventing extreme hazard to humans that all >> directions need to be clearly visible on the package as sold and provided >> options for doing so which could still reduce the size of Counter >> Assault's packaging. The UDAP packaging given to you as an example did

>> not allow all label text to be clearly visible. You explained that your

>> option 2 would be to reprint the text of the left and right panels, in at >> least 6 point font, on a card that could be slipped into the clamshell >> between the actual container and the plastic. The option selected by >> Counter Assault will be submitted to EPA as part of the final printed >> labeling. >> >> For item 2 (time to empty canister): you identified that the revised >> times, including the decimal place, simply could be included on the final >> printed labeling submitted to the Agency, with the cover letter referring >> to our discussion and your email. >> >> For item 5 ("produced by a grizzly encounter survivor"): We discussed >> the similarity of the requested text to that permitted on the competitive >> product and whether a graphic of Counter Assault's owner's face also >> could be included, similar to that permitted for the competitor. You >> agreed that, as long as the text and graphic are comparable in size and >> placement to that on the competitive product and do not detract from >> other labeling, those changes would be acceptable and could simply be >> submitted as part of the final printed labeling, referencing these >> communications. >> >> Please let me know if I have misunderstood any of our discussions. >> agreed upon changes will be included in the final printed labeling >> submitted to EPA associated with the July 8, 2004 label amendment >> acceptance for this product. >> Again, I very much appreciate your assistance in this. >> Regards. >> Elizabeth >> >> >> ----Original Message---->> From: Peacock.Dan@epamail.epa.gov [mailto:Peacock.Dan@epamail.epa.gov] >> Sent: Thursday, August 05, 2004 12:52 PM >> To: Elizabeth Brown >> Cc: Hebert.John@epamail.epa.gov >> Subject: Counter Assault Labeling Issues, EPA Reg. No. 55541-2 >> >> >> >> >> >> >> >> Elizabeth Brown, >> >> John and I enjoyed our visit with you last Thursday morning, July 28, >> 2004, to review the packaging of Counter Assault, Reg. No. 55541-2 and >> their chief competitor, UDAP's Pepper Power, EPA Reg. No. 72007-1 and to >> discuss your five labeling issues. I have summarized each issue below >> and provided a response. >> >> 1. Clamshell Packaging >> Description of Issue >> EPA required Counter Assault to repeat any text on the can label that >> was not clearly visible through the outer plastic packaging. In the >> packaging that you provided, Counter Assault repeated the Left and Right >> Panels, but not the Front Panel. This is acceptable to comply with 40 >> CFR 156.10(a)(4):

>>

>> Placement of Label-(i) General. >> ... If the immediate container is enclosed within a wrapper or outside >> container through which the label cannot be clearly read, the label must >> also be securely attached to such outside wrapper or container, if it is >> a part of the package as customarily distributed or sold. >> However, in the example provided of their competitor's product, UDAP did >> not repeat any text. Like Counter Assault, they should have also >> repeated the Left and Right Panels to comply with 40 CFR 156.10(a)(4). >> Counter Assault is complaining that UDAP's product is taking up only 2X >> the shelf space (by width) as UDAP and is increasing shipping costs for >> the bulkier product. >> Company Request >> They would like to be able to have packaging close to what UDAP has to >> address the two issues of increased shipping costs and shelf space. >> EPA Response to Counter Assault >> To comply with 40 CFR 156.10(a)(4), Counter Assault needs to repeat the >> texts of their Left and Right Panels on the back of their clam shell >> label by: >> >> 1.putting the text on the back of the card and to the left of the can >> (company's current practice); >> 2.putting the text of the Left and Right Panels between the back of the >> can and the plastic; or >> 3.adhering the text of the Left and Right Panels to the plastic itself. >> >> Using one of the above options would insure that all labeling was >> clearly visible, as required, and that the registrant saves the shipping >> and shelf space costs. >> EPA will inform the other three registrants of these options for product >> packaged in clamshells and of the need to comply at their next printing. >> >> ----->> >> 2. Time to Empty Canister >> Description of Issue >> The UDAP can label received from Ms. Brown and the last one accepted in >> the registration jacket says that it will empty in "5.4 seconds." EPA >> told Counter Assault that they could not say 7.2 or 9.2 seconds but made >> them round the figure down to an even number. >> Company Request >> Counter Assault would like to return to 7.2 and 9.2 seconds. >> >> EPA Response: >> We do not believe that the average user could tell whether the product >> discharged in 7.2 or 7 seconds and in 9.2 or 9 seconds. However, since >> we allowed the decimal point for UDAP, we will allow it for Counter >> Assault. >> >> >> 3. Addition of "The Bear Protection Experts" Claim >> Description of Issue >> Counter Assault would like to add the following marketing text, which is >> part of their logo:

>> The Bear Protection Experts >> EPA Response >> We will not allow this change as we have no way of substantiating such a >> claim, and it would only detract from other required labeling. >> >> 4. Addition of "Original Manufacturer of Counter Assault" Claim >> Description of Issue >> Counter Assault would like to add the following marketing text: >> original manufacturer of Counter Assault >> EPA Response >> We would not allow this type of statement as it would only detract from >> other required labeling. >> >> >> 5. Addition of "Produced by a Grizzly Encounter Survivor" Claim >> Description of Issue >> Counter Assault would like to add the following marketing text: >> Produced by a grizzly encounter survivor >> >> >> EPA Response >> We are a little uncertain about the exact meaning of the claim. >> statement might be acceptable if Counter Assault provided more details >> about the encounter since we allowed a related claim for their >> competitor's product, if it did not detract from other labeling (i.e., >> the type size was similar to his competitor). >> >> >> I hope that you found this response helpful. Let me know if you wish to >> discuss these issues further. >> Thank You, >> Daniel B. Peacock, Biologist >> Insecticide-Rodenticide Branch >> Registration Division (7504C) >> 1200 Pennsylvania Ave. NW >> Washington, DC 20460 >> Tel: 703-305-5407 >> Fax: 703 305-6596 >> E-Mail: peacock.dan@epa.gov >> >>

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Dan Peacock/DC/USEPA/US 11/06/2007 10:28 AM

To cgriffin@delta-ac.com

cc Bill Jacobs/DC/USEPA/US@EPA

bec

Subject 55541-2, Letter on Spray Pattern Testing

Dear Ms. Griffin,

Your 10/11/ 2007, letter and our 11/5/ telephone conversation clarified questions raised about Spray Pattern Testing.

I have addressed those questions in this E-Mail, which Mr. John Hebert has also reviewed.

Our basic review of such tests have not changed.

One of Counter Assaults major concerns was that, following EPA's previous review of Spray Pattern Data, it had approved a label in Nov 2004 with average (7.2 and 9.2), rather than minimum (7 and 9 sec) spray times, suggesting a change in test methodology.

A review of the administrative record for the product at the time reveals that the EPA earlier had approved a label in July 2004 on the condition
that the label spray times be adjusted to the minimum spray times of 7 and 9 seconds. When Counter Assault sent in revised label, we
overlooked the fact (Nov 2004) that Counter Assault had failed to make that label change. Therefore, at Counter Assault's next printing,
they need to make this label change and send us revised labeling.

Please let us know by E-Mail if Feb 11, 2008, would be an acceptable revised PRIA due date for this action. That date factors in 1 month of the testing and 3 mo for the review.



55541-2, spray pattern questions, 11-6-2007, p1. jpg



55541-2, spray pattern questions, 11-6-2007.jpg



55541-2, July 2004 label approval, with comments.tif



55541-2, Efficacy Review, 6-5-2007.pdf

Looks good...thanks.

john

Thank You,

Daniel B. Peacock, Biologist

Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

201.2 Efficacy Data

The spray pattern test report is cited and discussed below.

Griffin, C. and Johnson, P. (2007) Counter Assault Bear Deterrent EPA Reg. No. 55541-2 spray pattern. Unpublished report, Bushwacker Backpack and Supply Co., Inc. DBA Counter Assault, Kalispel, MT, and Delta Analytical Corporation, Inc., Silver Spring, MD, 5 pp. plus 4-page "CONFIDENTIAL APPENDIX".

MRID# 470668-01

This report is dated "February 21, 2007". Thus, it was completed between the application for clearance of "and the submission of 2/27/07. However, the report's "Procedure" paragraph, quoted in its entirety below, states that the trial was run on 9/11/06.

On September 11, 2006, Pride Johnson (Chemist) and Counter Assault employees conducted a study to verify the spray distance and spray duration (time) over which Counter Assault Bear Deterrent (AF) 230 grams travels. The study was conducted using twelve (12) laboratory-formulated samples sprayed outdoors in a small clearing in a heavily wooded area at approximately 9:30 AM with virtually no wind at approximately 75EF. In order to standardize the spray distance and pattern, distances of 26 to 34 feet were measured in 2 foot increments. Several cans of the Basic were sprayed and the spray distance and pattern were visually monitored. Next the AF was sprayed and the distance was compared to the spray distance of the Basic. Alternating the Basic spray time and distance with the AF spray time and distance provided a good comparison of the two. Subsequently, the AF was sprayed to establish the spray distance and the AF spray distance was recorded; the spray duration was recorded using a stopwatch.

As no raw data sheets accompany the Griffin and Johnson (2007) report, it is not

possible to determine whether the time of testing and the ambient temperature were recorded at any phase of the trials. As the trials could not have been completed instantaneously, a start time and a finish time should have been recorded at the very least. The ambient temperature probably changed somewhat over the course of time taken to complete the testing. Wind speed and direction should have been measured right before each individual canister was tested.

Spray distances ranging from 26 to 34 feet were reported for the 12 "AF of 230 grams" units tested. Each of these results was compared to the 30-foot distance listed on the "Basic Label (230g)", with 6 test canisters reportedly exceeding that distance, 4 equaling it, 2 falling short of it (by 2 and 4 feet). The "average" spray distance for the "AF of 230 Grams" was reported to be "31 feet", slightly farther than the "30 feet" claimed for the "Basic Label (230g)".

Spray durations ranging from 5.97 to 9.07 seconds were reported for the 12 "AF of 230 grams" test units. The reported "Average AF (230g)" spray time is "7.7 seconds", slightly more than the "7.2 seconds" reported for the "Basic Label (230g)".

Griffin and Johnson (2007) report no tests of the larger (290-g) Counter Assault container with the ""AF" in it. Instead, the authors estimate what the spray distances and durations for such a container might be.

Since the spray distance is almost identical and the spray duration is within 0.5 seconds (acceptable variation in operating stopwatch), a mathematical correlation for the AF 290 can is:

AF 290/230 (7.68)= 9.7 seconds 290/230(31)= 39 feet Basic Label = 9.2 seconds = 32 feet

According to this thinking, the ratio of the net contents of the two containers is directly translatable into ratios of spray duration and spray distance. The assumed relationship for spray duration at least seems plausible, if the two containers have the same orifice shape and dimensions, but should be tested rather than assumed. That there is more material in the larger can does not clearly mean that the absolutely greater amount of propellants would move the also-increased amounts of other product components farther, let alone proportionately farther based on a ratio of the net contents of the two containers. The propellants have to move a greater mass of material out of a larger container.

A "CONFIDENTIAL APPENDIX" to the Griffin and Johnson (2007) report compares a "Basic Formula" to an "Alternate Formula #2" in several ways related to composition and physical properties. The to formulations reportedly are very similar to identical in vapor pressure although the "Basic Formula" is somewhat higher in bulk density and in percent of the total formulation that is comprised of propellants. The "CONFIDENTIAL APPENDIX" also notes that the two formulations differ with respect to one propellant but have another in common. The formulations also reportedly differ in "Carrier/Solvent" composition, with "Alternate Formula #2" containing "

and "Basic Formula" containing"

,", which the

"Alternate Formulation" of 3/16/06 also reports.

As noted above, bear pepper sprays are used in what often may be life-or-death situations. Consequently, projected spray times and distances have no place on the labels for such products. Average times and distances also have no place on such labels. Averages consider all observed values, which is more than Griffin and Johnson (2007) actually did. They discarded the maximum and minimum results and averaged the middle 10. What belongs on the label are minimum times and effective spray distances on which a user can rely.

The shortest reported spray time for the "AF of 230 Grams" is 5.97 seconds, which rounds to 6 seconds. That is the maximum spray duration claim that should be considered for the "Alternate Formulation #2" described by the CSF of 12/20/06, in the event that the other hurdles to its adoption are cleared. It also should be noted that 4 of the reported spray durations for the "AF of 230 Grams" were below 7 seconds, while 5 were above 8 seconds. That the individual times were not clustered around the "Average" suggest either that there was poor quality control among containers and/or their contents or a lack of consistency in the way the trials were timed.

The statement to the effect that a half-second difference is "acceptable variation in operating stopwatch" seems forme. I have used stopwatches in timing behavioral events and athletic competitions, in the latter case usually with multiple watches and sometimes automatic timers as well. In such cases, discrepancies among timers as great as a full tenth of a second are very rare. I also have timed spray durations from videotaped tests of bear pepper sprays and generally have verified the accuracy of the times indicated in written reports of the same trials. It should be noted that spray times are to be measured from the onset of firing to the time when spray intensity begins to wane rather than on total "hiss" time. Due to the relatively large rectangular orifice on the container for a bear pepper spray products, it has been claimed that there is very little in the way of a fizzle hiss with such containers.

In tests run reportedly with the current "Basic" formulation (CSF of 11/24/03) for 55541-2, reported evacuation times for the 8.1-oz (230-g) container size rounded to or exceeded 7 seconds for all 5 cans, with one of the cans that were shaken before testing coming in at 6.96. A claim of approximately 7 seconds of spray time would be consistent with those data (see efficacy review of 6/29/04). However, IRB accepted a claim of ("approximately 7.2 seconds") without comment (label accepted on 11/22/04). The results for all 5 of the 230-g containers did average 7.2 seconds (see MRID# 461367 and efficacy review of 6/29/04). For the 290-g containers that reportedly had contained

¹ In a telephone conversation of 6/28/04, Pride Johnson of Counter Assault told me that the high concentration of propellants and the nature of the canister's spray orifice likely contributed to his observation that there is very little terminal hiss time in the evacuation of containers of bear pepper spray. He stated that the spray times reported to be for the revised "Basic" CSF of 11/24/03 represented the span from the onset of spraying to when the containers no longer were delivering a meaningful amount of material. That conversation pertained to the report of a spray pattern test that was assigned MRID# 461367-04.

the formulation described by the CSF of 11/24/03, evacuation times ranged from 9.08 to 9.32 seconds, with the mean time having been 9.2 seconds.² Such results are consistent with a label claim of approximately 9 seconds of spray duration. IRB accepted a claim of "approximately...9.2 seconds" for the 290-g container. In the container evacuation trials reported for the CSF of 11/24/03, containers were weighed before and after testing to determined how much material had been expelled from them. In all cases (5 containers per size), the reported drop in mass either met (when rounded) or exceeded the net contents claimed for the container.

The shortest spray distance reported for the "AF of 230 grams" is 26 feet. That would seem to be the only distance that could be claimed for the "Alternate Formulation #2" described by the CSF of 12/20/06. However, it is not clear how that distance was determined. If it was a linear distance along a substrate, that figure would not likely compare accurately to the distances determined for other bear pepper spray formulations, including the distances determined in earlier trials of COUNTER ASSAULT formulations.

The spray distance is the distance from the canister over which an effective (i.e., bear-deterrent) pattern and amount of aerosolized Capsaicin and related capsaicinoids can be delivered. To determine such a distance, one must shoot the product toward a vertical target kept a fixed distance from the canister. One then examines the pattern of impingements on the target, measuring vertical and horizontal "diameters". In the initial spray pattern test (MRID# 443369-05) submitted for the product that became 55541-2, the product literally was shot at the side of a barn (see efficacy review of 1/5/98).³ In the

2 In accepting "with COMMENTS" labeling for 7/8/04, IRB instructed Counter Assault to use 7 seconds and 9 seconds as the spray duration claims for the 230-g and 290-g containers, respectively. One of the registrant's agents subsequently (9/23/04) requested that 0.2 seconds be added to the claims for both container sizes (i.e., to use the mean time rather than the minimum to set the claims). IRB acceded to the request on 11/22/04. For reasons indicated in this review and in others, I maintain that the minimum guaranteed time – preferably expressed in whole seconds – is all that should be allowed to be claimed. That the average time was increased by several slow cans or slow timers is of no use to a person holding a quick can while being confronted by one or more bears. The differences between the mean and quickest spray duration times were on the order of ¼ second or less for the rather well-behaved (n=5) data reported under MRID# 461367-04). However, Griffin and Johnson (2007) report spray times ranging from 5.97 to 9.07 seconds for 230-g canisters reportedly containing "Alternate Formulation #2" and, excluding both extreme results, calculate an average spraying time of "7.7 seconds" – 1.73 seconds greater than the shortest observed time. Personally, I would like to know if I were holding what might only be a 6-second can.

In the world of competitive promotion of bear pepper sprays, spray duration claims have become a big deal. That every fraction of a second "counts" in that arena probably is why the request of 9/23/04 was made on Counter Assault's behalf. Claiming 7.2 (or 7.7) seconds for a product with containers that might only hold 6 seconds of useful spray would be a "false or misleading" label statement.

³ In our telephone conversation of 6/28/04, Johnson told me that Bushwacker's President William Pounds had conducted those trials inside the barn. Johnson noted that he conducted his tests outdoors so as not to expose test personnel to airborne pepper spray in a confined space.

spray pattern trials reported (MRID# 461367-04) for the higher-strength formulation described by the CSF of 11/24/03, the target was an outside wall of an outbuilding (see efficacy review of 6/29/04). In both trial, spray diameters were reported. Spray diameters were measured on vertical targets which were inspected visually and by taste to determine whether material consistent with the product in appearance and/or pungency had impinged on the targets.

That different spray distances are reported for the various "AF of 230 Grams" containers used strongly suggests that distances were determined by a means other than use of a fixed vertical target. The Griffin and Johnson (2007) report does not discuss spray pattern diameters. That report also fails to mention vertical targets, let alone visual and taste assessments of them. Without use of a vertical target, data on spray pattern diameters would have been almost impossible to collect.

Taken at face value, the results reported by Griffin and Johnson (2007) are consistent with a claim of "approximately 6 seconds" for the formulation that they tested in 230-g containers. Taking Griffin and Johnson (2007) at their word regarding spray distance would limit the distance claim to 26 feet. As it seems unlikely that vertical targets were used, the data on which that claim would have to be based are suspect.

The primary Griffin and Johnson (2007) report ends with the "Conclusion" text quoted below.

The Test Parameters assumed that since the Bulk Density, the Percent of Propellant and Propellant's Vapor Pressure are very similar; [sic] the spray distance and spray duration would also be very similar. The study verified this hypothesis; the AF spray duration and distance are similar to, or exceed the Basic. However, Counter Assault wants the labeling on the formulated product with the AF to remain the same as labeling formulated with the Basic. Therefore, Counter Assault is not requesting changes to the current EPA approved labeling at this time.

At a future date if the Basic is eliminated and the AF becomes the only formula, Counter Assault may request an amendment to the labeling to reflect the results of this study as follows:

Size	Duration	Distance
230	7.5 seconds	31 feet
290	9.5 seconds	36 feet

For reasons discussed above, no distance claims are supported for the formulation described by the CSF of 12/20/06 in the 230-g canister and no claims of distance or duration were tested – much less supported – for the 290-g container. The minimum reported spray duration for "Alternate Formulation #2" was 5.97 seconds, consistent with a claim of "approximately 6 seconds". Consequently, acceptance of the CSF of 12/20/06 based on the spray data received thus far would require that the spray duration claimed on the label for the 8.1-oz container be shortened from "approximately 7.2 seconds" to "approximately 6 seconds" to accommodate all formulations that might be used for

55541-2. (If "Alternative Formulation #2" is not accepted, the duration claims should be changed to "approximately 7 seconds" and "approximately 9 seconds" for the 8.1-oz and 10.2-oz containers, respectively.) As for spray distance, we would have to choose between allowing the 30-foot claim to stand for all formulations in the 8.1-oz container or to reduce the claim to 26 feet based upon the lowest value reportedly observed for the most recently submitted alternate formulation.

As the inert ingredient was not cleared, discussions of label claims pertinent to the CSF of 12/20/06 may be postponed until such time, if any, that the ingredient is cleared.

The take-home message from this review should be that spray pattern tests must be conducted appropriately for their results to be useful. If trials are conducted outdoors, wind speeds and directions should be measured before each individual trial and should be verified as having been minimal. The person doing the spraying should be a measured fixed distance from a vertical target covered with a material (e.g. white paper or linen) that will readily show impacts of spray particles and that can be removed and replaced between succeeding trials. The distance between the sprayer and the target should be manipulated as an independent variable. Typically, that would be accomplished by moving the person closer or farther from the target rather than by moving the target. The vertical and horizontal dimensions of the pattern of impingement should be measured and reported to gauge the cross-sectional area of the spray cloud when it reaches the target. As Griffin and Johnson (2007) seem not to have performed the procedures appropriate for a spray pattern test, the most that should be taken from their report is the information regarding evacuation times for the 230-g container.





Bill Jacobs/DC/USEPA/US 10/24/2007 02:20 PM To Dan Peacock/DC/USEPA/US@EPA, cgriffin@delta-ac.com

CC

bcc

Subject Re: Fw: Counter Assault inert and spray pattern study

The spray duration claim is essentially a guarantee of about how many seconds of useful spray a container will deliver. Therefore, the minimum spray duration obtained with the containers evacuated for that test is the number that should be used. It is correct that the spray duration should be timed from the onset of spraying until the time when the container is no longer delivering a useful spray (as opposed to the end of the hiss). If an abnormally short spray duration is obtained in testing due to a problem with the timer or with the handling of the canister, that value must be noted but would not be used for the label statement. If a canister is handled and timed appropriately and a short duration is recorded for it, that time should be adopted as the spray duration as it can reasonably be expected that other containers will evacuate as rapidly as that one.

The spray duration claimed generally should be reported in terms of a the nearest whole number of seconds that meets or falls below the minimum spray time. (If the minimum time is very close to the next whole-second, rounding up would be reasonable. For example, a timed and reported duration of 5.96 seconds would be considered to be equivalent to 6 seconds.) Whole-second times are hard enough for the average person to judge or appreciate. Judging tenths of seconds into the would be that much harder. However, reports of test times must be expressed using the same number of decimal places that were used on the timing mechanism. If the stop-watch indicates results to hundredths of seconds, the recorded time must be expressed to that level of "accuracy".

Spray distance is determined by documentation that spray reaches and leaves a detectable residue on a vertical object stationed a fixed distance from the user. Given that past tests with Counter Assault have shown spray distance to be on the order of 30-35', it probably would be a good idea to begin testing (on a low--wind day) with the user situated 30' from the target. Canister sizes that deliver visible residue at that distance could then be tested at 35'. Any canister sizes that fail to deliver visible residue at 30' could be tested at a shorter distance (e.g., 25'). This method of testing would not give an average distance, but that is not what is needed. What the user needs to know is from how far away the spray reliably will reach and, presumably, affect the bear.

Similar mean (average) spray durations and distances could be obtained with widely varying results for individual canisters. For example, spray durations of 7.2, 7.0, 6.8, and 7.0 seconds for one product and 4.0, 12.0, 5.1, and 6.9 seconds for another would yield the same mean time (7.0 seconds); but claiming that figure for the second product would not prepare users for the "quick" containers that they might well encounter.

It is recommended (but not required) that spray pettern tests be video-recorded. Submitting video records of the actual testing can serve to resolve most questions that might arise regerding procedures and results.

Dan Peacock/DC/USEPA/US

Dan Peacock/DC/USEPA/US 10/24/2007 12:59 PM

To Bill Jacobs/DC/USEPA/US@EPA

CC

Subject Fw: 'Counter Assault inert and spray pattern study

Bill,

Counter Assault needed answers to these questions about the spray pattern test. I can give you a bean Thursday. Off this PM

Thank You,

Daniel B. Peacock, Biologist Tel: 703-305-5407

Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

--- Forwarded by Dan Peacock/DC/USEPA/US on 10/24/2007 12:58 PM ---



"Cristina Griffin" <cgriffin@delta-ac.com> 10/11/2007 02:42 PM

To Dan Peacock/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA

CC

Subject Counter Assault inert and spray pattern study

Dan and John.

Attached to this e-mail is a letter regarding the inert and spray pattern study. We also are mailing the letter so that you will have the original.

Dan, we had already drafted the letter when we received your e-mails yesterday regarding the need for a formal letter approving the inert; this letter requests formal confirmation of the inert approval, as we have discussed. In addition, the letter asks for clarification of requirements for the spray pattern study. As the letter explains, Counter Assault was ready to conduct the study when I pointed out EPA's comments on the most recent study submitted. We need clarification as soon as possible so the study can be conducted before the weather turns too cold.

Thanks for your help. If you have any questions, please call.

Best Regards,
Cristina Griffin
Delta Analytical Corp.
e-mail: cgriffin@delta-ac.com
voice: 301-680-7971

fax: 301-680-7975

12510 Prosperity Drive, Suite 160

Silver Spring MD 20904



Spray Pattern Information on Test # # of replications copy of review I working a 3) spray fine 4) average -5) weags -6 Lengthed -> emtyrn

letter •



John Hebert/DC/USEPA/US 10/25/2007 02:26 PM

To Dan Peacock/DC/USEPA/US@EPA

CC

bcc

Subject Re: Fw: question on spray pattern RE: 55541-2, Letter Approving New, Non-Food Inert

History:

This message has been replied to.

Is the propellent changing?

Dan Peacock/DC/USEPA/US



Dan Peacock/DC/USEPA/US 10/24/2007 08:06 PM

To John Hebert/DC/USEPA/US@EPA

CC

Subject Re: Fw: question on spray pattern RE: 55541-2, Letter Approving New, Non-Food Inert

John,

We are requiring these data because the registrant is changing a very large percentage of the inerts in the formula (>30%), including the new, non-food inert and other inerts.

The spray pattern is one part of the data obtained. Other components include the total time to discharge the entire product and the number of 1 sec bursts in a single can.

These data are critical to the efficacy of a product for which failure is death.

Thank You,

Daniel B. Peacock, Biologist Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

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John Hebert/DC/USEPA/US



John Hebert/DC/USEPA/US 10/24/2007 04:43 PM

To Dan Peacock/DC/USEPA/US@EPA

CC

Subject Fw: question on spray pattern RE: 55541-2, Letter Approving New, Non-Food inert



John Hebert/DC/USEPA/US 10/24/2007 04:43 PM

To Dan Peacock/DC/USEPA/US@EPA

CC

bcc

Subject Fw: question on spray pattern RE: 55541-2, Letter Approving New, Non-Food Inert

History:

This message has been replied to.

dan - please remind me again why we are requiring this spray pattern data? is it b/c of the new inert? or is it due to a change in package size?

john

--- Forwarded by John Hebert/DC/USEPA/US on 10/24/2007 04:40 PM ----



"Cristina Griffin" <cgriffin@delta-ac.com> 10/24/2007 02:04 PM

To Dan Peacock/DC/USEPA/US@EPA

cc "Pride Johnson" <pri>pride@counterassault.com>, John Hebert/DC/USEPA/US@EPA

Subject question on spray pattern RE: 55541-2, Letter Approving New, Non-Food Inert

Dan,

Thank you for your letter of Oct 24, 2007 approving the inert for use in Counter Assault Bear Deterrent.

In section "B. Spray Pattern Data" you note that the spray pattern study needs to be conducted and you discuss the PRIA due date. Counter Assault cannot conduct a spray pattern study, however, until EPA answers the questions we asked in our letter to you dated October 11, 2007. I have attached the letter again to this e-mail for your convenience. In the section of the letter entitled "Confirmation regarding using previous methodology for spray pattern study" we ask several specific questions we need answered. Please check on this and let us know how to proceed. Then Counter Assault can work on conducting the spray pattern study and submitting it to you.

Best Regards, Cristina Griffin Delta Analytical Corp. e-mail: cgriffin@delta-ac.com voice: 301-680-7971 fax: 301-680-7975 12510 Prosperity Drive, Suite 160 Silver Spring MD 20904

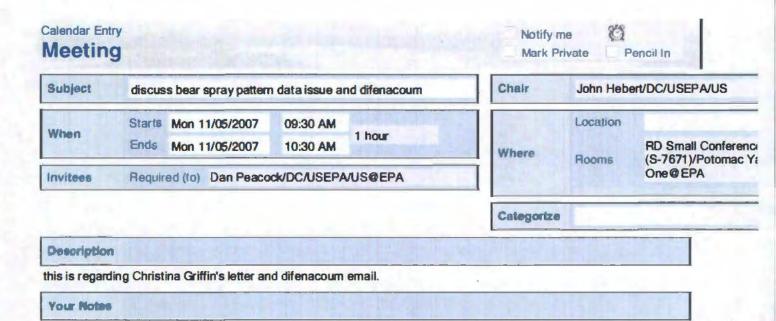
Original Message----

From: Peacock.Dan@epamail.epa.gov [mailto:Peacock.Dan@epamail.epa.gov]

Sent: Wednesday, October 24, 2007 6:28 AM

To: cgriffin@delta ac.com

Subject: 55541-2, Letter Approving New, Non Food Inert





Dan Peacock/DC/USEPA/US 10/24/2007 07:38 PM

To Bill Jacobs/DC/USEPA/US@EPA

CC

bcc

Subject Fw: question on spray pattern RE: 55541-2, Letter Approving New, Non-Food Inert

Additional Information from Cristina Griffin:

Daniel B. Peacock, Biologist

Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

---- Forwarded by Dan Peacock/DC/USEPA/US on 10/24/2007 07:37 PM ----



"Cristina Griffin" <cgriffin@delta-ac.com> 10/24/2007 02:04 PM

- To Dan Peacock/DC/USEPA/US@EPA
- cc "Pride Johnson" <pri>pride@counterassault.com>, John Hebert/DC/USEPA/US@EPA

Subject question on spray pattern RE: 55541-2, Letter Approving New, Non-Food Inert

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Best Regards, Cristina Griffin Delta Analytical Corp. e-mail: cgriffin@delta-ac.com voice: 301-680-7971 fax: 301 680 7975 12510 Prosperity Drive, Suite 160 Silver Spring MD 20904 - - - Original Message---

From: Peacock.Dan@epamail.epa.gov [mailto:Peacock.Dan@epamail.epa.gov]

Sent: Wednesday, October 24, 2007 6:28 AM

To: cgriffin@delta-ac.com

Subject: 55541-2, Letter Approving New, Non-Food Inert

I corrected a type at end of letter. The correct, proposed PRIA date was Feb 12, 2008.

Dear Cristina,

Here is the official letter that you requested for the approval of the new, non-food inert:

(See attached file: 55541-2, 10-24-2007 ltr.pdf)

Please provide feedback about re-negotiating the PRIA Due Date for this action from 11-12-2007 to 2 11-2008.

Thank You,

Daniel B. Peacock, Biologist

Tel: 703 305 5407 Fax: 703-305 6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

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letter to EPA re CSF amendment.PDF



John Hebert/DC/USEPA/US 10/25/2007 12:48 PM To Dan Peacock/DC/USEPA/US@EPA

CC

bcc

Subject Fw: question on spray pattern RE: 55541-2, Letter Approving New, Non-Food Inert

i thought you might be amused by this....this is a bear pepper spray product that we got the complaint (notebook) about. i think i might push back a little and have some fun with this. he hates it when i question him about stuff like this.

--- Forwarded by John Hebert/DC/USEPA/US on 10/25/2007 12:42 PM ---

Dan Peacock/DC/USEPA/US 10/24/2007 08:06 PM

To John Hebert/DC/USEPA/US@EPA

CC

Subject Re: Fw: question on spray pattern RE: 55541-2, Letter Approving New, Non-Food Inert

John,

We are requiring these data because the registrant is changing a very large percentage of the inerts in the formula (>30%), including the new, non-food inert and other inerts.

The spray pattern is one part of the data obtained. Other components include the total time to discharge the entire product and the number of 1 sec bursts in a single can.

These data are critical to the efficacy of a product for which failure is death.

Thank You,

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Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

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John Hebert/DC/USEPA/US



John Hebert/DC/USEPA/US 10/24/2007 04:43 PM

To Dan Peacock/DC/USEPA/US@EPA

CC

Subject Fw. question on spray pattern RE: 55541-2, Letter Approving New, Non-Food Inert dan - please remind me again why we are requiring this spray pattern data? is it b/c of the new inert? or is it due to a change in package size?

john

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"Cristina Griffin" <cgriffin@delta-ac.com> 10/24/2007 02:04 PM

To Dan Peacock/DC/USEPA/US@EPA

cc "'Pride Johnson'" <pride@counterassault.com>, John Hebert/DC/USEPA/US@EPA

Subject question on spray pattern RE: 55541-2, Letter Approving New, Non-Food Inert

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Best Regards, Cristina Griffin Delta Analytical Corp. e mail: cgriffin@delta ac.com voice: 301-680-7971 fax: 301 680 7975 12510 Prosperity Drive, Suite 160 Silver Spring MD 20904

----Original Message-

From: Peacock.Dan@epamail.epa.gov [mailto:Peacock.Dan@epamail.epa.gov]

Sent: Wednesday, October 24, 2007 6:28 AM

To: cgriffin@delta-ac.com

Subject: 55541-2, Letter Approving New, Non-Food Inert

I corrected a type at end of letter. The correct, proposed PRIA date was Feb 12, 2008.

Dear Cristina,

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(See attached file: 55541 2, 10 24-2007 ltr.pdf)

Please provide feedback about re-negotiating the PRIA Due Date for this action from 11-12-2007 to 2-11 2008.

Thank You,

Daniel B. Peacock, Biologist

Tel: 703-305-5407 Fax: 703 305-6920

E-Mail: peacock.dan@epa.gov

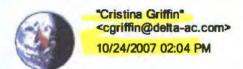
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- A

letter to EPA re CSF amendment.PDF



To Dan Peacock/DC/USEPA/US@EPA

bcc

Subject question on spray pattern RE: 55541-2, Letter Approving New, Non-Food Inert

History:

This message has been replied to and forwarded.

Dan,

Thank you for your letter of Oct 24, 2007 approving the inert for use in Counter Assault Bear Deterrent.

In section "B. Spray Pattern Data" you note that the spray pattern study needs to be conducted and you discuss the PRIA due date. Counter Assault cannot conduct a spray pattern study, however, until EPA answers the questions we asked in our letter to you dated October 11, 2007. I have attached the letter again to this e-mail for your convenience. In the section of the letter entitled "Confirmation regarding using previous methodology for spray pattern study" we ask several specific questions we need answered. Please check on this and let us know how to proceed. Then Counter Assault can work on conducting the spray pattern study and submitting it to you.

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Sent: Wednesday, October 24, 2007 6:28 AM

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Please provide feedback about re-negotiating the PRIA Due Date for this action from 11 12-2007 to 2 11-2008.

Thank You,

Daniel B. Peacock, Biologist

Tel: 703-305-5407 Fax: 703-305-6920

E Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

POP .

letter to EPA re CSF amendment PDF



1) must test each can 2) must include the data

202.0 CONCLUSIONS

 The report of spray patterns and spray durations by Griffin and Johnson (2007, MRID No. 470668-01) lacks sufficient detail to be usable as a spray pattern study. It is not clear from the report how effective spray distances were determined, and no data on spray pattern dimensions are reported.

The information on spray durations for 230-g (8.1-oz) canisters included in the Griffin and Johnson (2007) report indicates considerable variation in spray times among containers and/or difficulties in the procedures used to determine spray times. As the minimum spray time reported (5.97 seconds) rounds to 6 seconds, the most that could be claimed based upon the reported test results is a minimum spray time of "approximately 6 seconds", which is lower than the claim that appears on the current accepted label for the 8.1-oz container of this product.

2. The Griffin and Johnson (2007) report does not describe testing of 290-g (10.2-oz) containers for spray characteristics. Rather, spray durations and distances reportedly were extrapolated for them using "average" results (minus highest and lowest values) for the 230-g container and assumptions of proportionality in spray duration and distance based upon the ratio of the net contents of the two containers and similarities in the physical properties of the proposed "Alternative Formulation #2" and the formulation that allegedly was used in prior tests. Using average scores

2309(8.1

ret tested

Inert ingredient information may be entitled to confidential treatment

is not appropriate for values that are essentially to be guarantees. While a positive correlation contents and evacuation times seems likely to exist, it is not clear that there would be such a relationship for spray distances.

The spray duration and distance claims that Griffin and Johnson (2007) indicate in their "Conclusion" paragraphs that Counter Assault might want to make in the event that "the AF becomes the only formula" for 55541-2 do not track with the authors' data and projections from earlier in the report and would not be acceptable in any case based upon the nature and quality of their report.

Bear pepper sprays are used in what often may be life-or-death situations.
 Therefore, there is no room for error or exaggeration regarding information on spray durations or distances. The times and distances claimed should be minimums that can be expected reliably. Consequently, each container size and formulation must be tested for such properties.

Spray duration is to be timed from the onset of firing until the container ceases to deliver a cloud of material suitable for deterring bears, rather than from the onset of firing until nothing comes out of the container.

Spray pattern tests must be conducted appropriately for their results to be of value. If tests are conducted outdoors, wind speeds and directions should be measured for each individual trial and should be verified as having been minimal before the trial is attempted. The person doing the spraying should be a measured fixed distance from a vertical target covered with a material (e.g. white paper or linen) that will readily show impact of spray particles and that can be removed and replaced between succeeding trials. The distance between the sprayer and the target should be manipulated as an independent variable. Typically, that would be accomplished by moving the person closer or farther from the target rather than by moving the target. The vertical and horizontal dimensions of the pattern of impingement should be measured and reported to gauge the cross-sectional area of the spray cloud when it reaches the target.

4. Due to the rejection of as an ingredient for this product, its composition and labeling should remain consistent with the performance of the current accepted formulation(s). The spray distance claims should remain at 30 feet for the 8.1-g container and 32 feet for the 10.2-g container. The spray duration claims should be changed to "approximately 7 seconds" for the 8.1-g container and "approximately 9 seconds" for the 10.2-g container. Those times approximate the minimum times that were reported for containers of those sizes for the basic formulation of this product.

William W. Jacobs Biologist Insecticide-Rodenticide Branch June 5, 2007



Dan Peacock/DC/USEPA/US 10/24/2007 08:19 PM

To Bill Jacobs/DC/USEPA/US@EPA

CC

bcc

Subject Fw: question on spray pattern RE: 55541-2, Letter Approving New, Non-Food Inert

Bill,

Attached is my response to John Hebert Hopefully, that will clarify the critical need for these data. In giving information to Christina, make sure that knows exactly what we expect so that, if they do not follow our instructions, we can produce a clear document that explains, point by point, what we expect.

I know that they need to:

1. test each can size (They have 3 sizes.)

2. record the spray pattern as the height and width of the spray cloud at specific distances (like 10', 15',

20', 25', etc)

3. record the total discharge time from start to finish (you have a definition of "start" and "finish", which you need to give them)

(measured in 0.1 200)

4, record the total number of 1 sec bursts in one can

5. repeat the tests with I number of cans (We need to tell them the number.)

6. supply a video tape, # possible, as it will help us to interpret the test, even if not done perfectly.

Thank You,

Daniel B. Peacock, Biologist

Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

--- Forwarded by Dan Peacock/DC/USEPA/US on 10/24/2007 08:07 PM ----



Dan Peacock/DC/USEPA/US 10/24/2007 08:06 PM

To John Hebert/DC/USEPA/US

CC

Subject Re: Fw: question on spray pattern RE: 55541-2, Letter Approving New, Non-Food Inert

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John Hebert/DC/USEPA/US



John Hebert/DC/USEPA/US 10/24/2007 04:43 PM

To Dan Peacock/DC/USEPA/US@EPA

CC

Subject Fw: question on spray pattern RE: 55541-2, Letter Approving New. Non-Food Inert

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john

---- Forwarded by John Hebert/DC/USEPA/US on 10/24/2007 04:40 PM ----



"Cristina Griffin" <cgriffin@delta-ac.com> 10/24/2007 02:04 PM

To Dan Peacock/DC/USEPA/US@EPA

cc "Pride Johnson" <pri>cc "Pride@counterassault.com>, John Hebert/DC/USEPA/US@EPA

Subject question on spray pattern RE: 55541-2, Letter Approving New, Non-Food Inert

Dan

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Best Regards, Cristina Griffin Delta Analytical Corp. e-mail: cgriffin@delta-ac.com voice: 301 680-7971 fax: 301-680-7975 12510 Prosperity Drive, Suite 160 Silver Spring MD 20904

----Original Message -- -

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Sent: Wednesday, October 24, 2007 6:28 AM

To: cgriffin@delta ac.com

Subject: 55541-2, Letter Approving New, Non-Food Inert

I corrected a type at end of letter. The correct, proposed PRIA date was Feb 12, 2008.

Dear Cristina,

Here is the official letter that you requested for the approval of the new, non-food inert:

(See attached file: 55541-2, 10-24-2007 ltr.pdf)

Please provide feedback about re-negotiating the PRIA Due Date for this action from 11-12-2007 to 2 11-2008.

Thank You,

Daniel B. Peacock, Biologist

Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

TOTAL STATE OF THE PARTY OF THE

letter to EPA re CSF amendment PDF



Dan Peacock/DC/USEPA/US 10/24/2007 07:21 AM

To cgriffin@delta-ac.com

CC

bcc

Subject 55541-2, Letter Approving New, Non-Food Inert

Dear Cristina,

Here is the official letter that you requested for the approval of the new, non-food inert:



 Please provide feedback about re-negotiating the PRIA Due Date for this action from 11-12-2007 to 2-11-2008.

Thank You,

Daniel B. Peacock, Biologist Tel: 703-305-5407

Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

October 24, 2007 E-Mail

Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904

Attention: Ms. Cristina Griffin

Subject: Counter Assault Bear Deterrent

EPA Reg. No. 55541-2

Your amended application of December 20, 2006

Your resubmission of February 27, 2007

Our letter of July 2, 2007 Our meeting of July 19, 2007

Purpose The purpose of this submission, under section 3 of the Federal Insecticide,

Fungicide, and Rodenticide Act (FIFRA), is to replace your existing Confidential Statements of Formula (CSF), November 24, 2003, and March 16, 2006, with a new CSF, dated December 20, 2006, including a new inert ingredient not found in any currently registered product.

Review A. New Non-Food Inert

1. Initial Review

Based on our initial review communicated in our July 2, 2007, letter, we were not able to approve your new inert because of the toxicity profile of the new, non-food inert.

For that initial assessment, we did not consider the amount of minimal exposure to the environment from a bear repellent. Normally, for new, non-food inerts, we must consider exposure from all potential uses.

Review -

2. July 19, 2007, Meeting

At this meeting we discussed additional information that you had provided the Agency and agreed to reconsider our initial decision **not** to permit the inclusion of the new, non-food inert in your bear repellent.

3. Reconsideration of New, Non-Food Inert in a Bear Repellent

After further consider, we have determined that we will, in fact, allow the use of your proposed new, non-food inert in your bear repellent product. We will only allow this inert to be used in bear repellent products, not for any other use site, including food.

B. Spray Pattern Data

- Because the initial spray pattern data were unacceptable, you will need to repeat those data for each can size for the new formula.
- 2. Because of the additional time needed to develop and to review these data, we will need to re-negotiate the PRIA due date, which expires on November 12, 2007. How much time would you need to conduct these studies? If you can send us the new data within one (1) month, we would propose to extend the PRIA due date until February 12, 2008. Would this new date be acceptable to you? If so, send us an E-Mail stating that you would project sending in the new spray pattern data by December 12, 2007, and would request an extension of the PRIA Due Date of three (3) months, or February 12, 2008.

Questions

If you have questions about this letter, please contact me at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock.dan@epa.gov (by E-Mail).

Sincerely yours,

Daniel B. Peacock, Biologist Insecticide-Rodenticide Branch

Daniel B. Rearch

Registration Division (7504C)

Dan Peacock, Flash Drive, 2gb, P:\Documents\Word, WP, Excel, etc\Capsaicin\55541-2\New Non-food Inert\55541-2, new CSF, new inert, 10-24-2007.doc

Inert ingredient information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIOES AND TOXIC SUBSTANCES

> Eontains CBI

October 17, 2007

MEMORANDUM

SUBJECT: Approval of

For Use Only In

Bear Repellents

FROM: Deborah McCall, Acting Branch Chief

Inert Ingredient Assessment Branch

Registration Division (7505P)

TO: Dan Peacock

Insecticide - Rodenticide Branch Registration Division (7505P)

The Inert Ingredient Assessment Branch (IIAB) has approved the use of

as a inert ingredient that can only be used in pesticide products applied as bear repellents. This chemical is not approved for use in pesticides applied to any other use site, including food. A record has been created in OPPIN that clearly stipulates that the chemical can only be used in bear repellents.

Please contact Karen Angulo (703-306-0404) with questions.



Dan Peacock/DC/USEPA/US 09/13/2007 10:42 AM

To Karen Angulo/DC/USEPA/US@EPA

CC

bcc

Subject Re: Fw: Counter Assault inert ingredient

Karen,

•

I left the information as a voicemail message.

The package is in my Cube 7262 on my "spare chair".

Thank You,

Daniel B. Peacock, Biologist Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

Karen Angulo/DC/USEPA/US



Karen Angulo/DC/USEPA/US 09/12/2007 01:07 PM

To Dan Peacock/DC/USEPA/US@EPA

C

Subject Re: Fw: Counter Assault inert ingredient

Hello Dan,

We have decided to approve this chemical for use only in products that are non-food use and only bear repellents. A record will be created in OPPIN that clearly stipulates that the chemical can only be used in bear repellents.

Could you please send me the chemical name and CAS number the registrant is asking for? Pauline had that information and I can't locate it. Thanks.

Thanks,

Karen Angulo
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505C)
703-306-0404
angulo.karen@epa.gov

Dan Peacock/DC/USEPA/US



Dan Peacock/DC/USEPA/US

09/11/2007 11:44 AM

To Karen Angulo/DC/USEPA/US@EPA

CC

Subject Fw: Counter Assault inert ingredient

Karen,

Could you check on this question with the acting Branch Chief, Debbie McCall?

Will nothing happen until there is a permanent replacement?

 I need to inform Christina Griffin of Delta Analytical, agent for Counter Assault. They had the new, non-food inert. The co wanted us to approve it based on exposure and as an acceptable alternative to other VOC chemicals in the Air Program. A decision could have a lot of resource consequences so we want to proceed wisely.

Thank You,

Daniel B. Peacock, Biologist

Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

---- Forwarded by Dan Peacock/DC/USEPA/US on 09/11/2007 11:44 AM ----



Dan Peacock/DC/USEPA/US

09/11/2007 11:39 AM

To "Cristina Griffin" <cgriffin@delta-ac.com>

CC

Subject Re: Counter Assault inert ingredient

Cristina,

I will check again. Since we last talked the Chief of the Inerts Branch, Pauline Wagner, suddenly retired. That is an unexpected development, which will likely slow down an answer. However, I will check. They may want to wait until there is a permanent replacement before acting on such an important policy issue. Will be you know.

Thank You,

Daniel B. Peacock, Biologist

Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

"Cristina Griffin" <cgriffin@delta-ac.com>



"Cristina Griffin" <cgriffin@delta-ac.com> 09/11/2007 11:22 AM

To Dan Peacock/DC/USEPA/US@EPA

CC

Subject Counter Assault inert ingredient

Dan,

Could you please check with the inerts staff regarding decisions and next steps on the inert ingredient. As you know, the PRIA clock is ticking on Counter Assault being able to accomplish the next steps. Please let me know. Or if I need to contact someone on the inerts staff, let me know.

Best Regards, Cristina Griffin Delta Analytical Corp. e-mail: cgriffin@delta-ac.com

voice: 301-680-7971 fax: 301-680-7975

12510 Prosperity Drive, Suite 160

Silver Spring MD 20904

Propellant





To Pauline Wagner/DC/USEPA/US@EPA, Bill Jacobs/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA, Karen Angulo/DC/USEPA/US@EPA, Kerry Leifer/DC/USEPA/US@EPA

CC

bcc

Subject Fw: Background paper for meeting on Thursday at 1pm

ALL,

Counter Assault's agent, Cristina Griffin, asked me to forward this background information for our meeting on Thursday, July 19, 1PM about the new non-food inert that we turned down.

The purpose of the meeting is for the company and EPA to share our respective perspectives, to the extend possible, on approving new, non-food inerts, based, in part, on exposure and as alternatives to other inerts that the Air Program is phasing out.

I will have to find another meeting room as the one requested was booked. I will let everyone know Wed. Let me know if you have any questions.

John and Kerry: Will you be attending?

Thank You,

Daniel B. Peacock, Biologist

Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

---- Forwarded by Dan Peacock/DC/USEPA/US on 07/17/2007 03:44 PM ----



"Cristina Griffin" <cgriffin@delta-ac.com> 07/17/2007 03:28 PM

To Dan Peacock/DC/USEPA/US@EPA



cc "Pride Johnson" <pride@counterassault.com>
Subject Background paper for meeting on Thursday at 1pm

Dan,

As we discussed, here is the background paper for our meeting on Thursday July 19.

Best Regards, Cristina Griffin Delta Analytical Corp.

e-mail: cgriffin@delta-ac.com

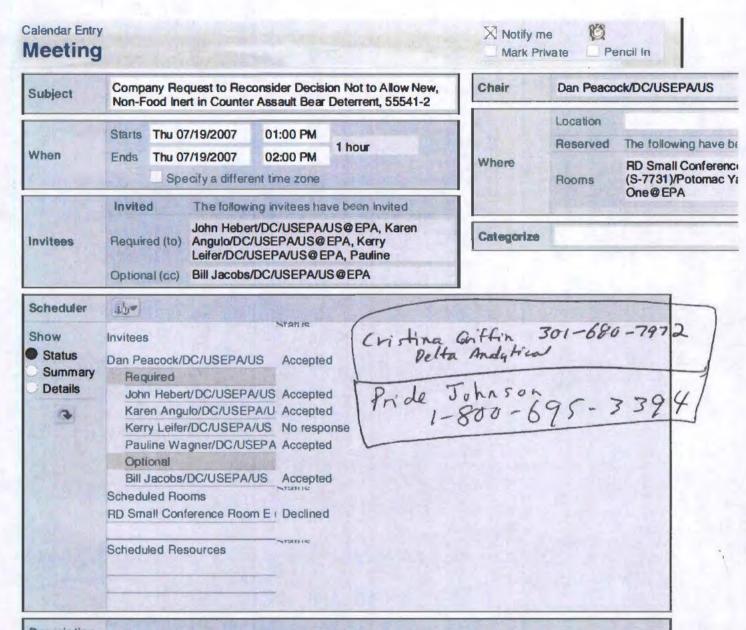
voice: 301-680-7971 fax: 301-680-7975

12510 Prosperity Drive, Suite 160

Silver Spring MD 20904

background for Counter Assault-EPA mtg.doc





Description

- Cristina Griffin, agent to Counter Assault, and Pride Johnson, President of Counter Assault have requested this
 meeting to request EPA to reconsider their decision not to allow a new inert in this product.
- They will explain their position at the meeting, and EPA will explain their position.
- Ms. Griffin will be physically present, and Mr. Johnson will join us by phone.
- Ms. Griffin has promised to outline their position in a document and supply it no later than Monday, July 16, COB.
 When it arrives, I will forward it to meeting participants.
- Their major points are 1) that EPA should consider exposure in its assessment for new, non-food inerts and 2) that EPA should consider that the Air and Radiation Program permits the new inert as a substitute for the one currently in their product.
- My phone is 703-305-5407 if there are questions.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

305 5-803017 1130 R-34 5-806184

July 2, 2007

Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904

Attention: Ms. Cristina Griffin

Subject: Counter Assault Bear Deterrent

EPA Reg. No. 55541-2

Your amended application of December 20, 2006

Your resubmission of February 27, 2007 Request to Withdraw Amendment

Purpose

The purpose of this submission, under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is to replace your existing Confidential Statements of Formula (CSF), November 24, 2003, and March 16, 2006, with a new CSF, dated December 20, 2006, including a new inert ingredient not found in any currently registered product.

Review A. New Non-Food Inert

We have reviewed the data package on the new inert (no MRID assigned) and the new spray pattern data (MRID No. 470668-01) to support this amendment.

Based on the information provided, we are not able to approve the requested use of the new, non-food inert and its associated CSF. We have concerns about the mammalian and aquatic toxicity of the ingredient. We have attached a copy of our review.

B. Spray Pattern Data

 The report lacks sufficient detail to assess spray pattern. It was not clear how the authors determined spray distances. Also, the study lacked data on spray pattern dimensions.

- 2. For the spray durations for the 230g (8.1 oz) canisters, the most that could be claimed would be "approximately 6 seconds" for this size of container. There was no specific test for the 290g (10.2 oz) canisters.
- You will find additional details in the conclusions of our review of this study in the Enclosure 2, which will assist you if you run such tests in the future.
- 4. The spray duration claims should be changed to "approximately 7 seconds" for the 8.1g container and "approximately 9 seconds" for the 10.2g container. Those times approximate the minimum times that were reported for containers of those sizes for the basic formulation of this product.

Request to Withdraw

Because we cannot approve the new, non-food inert, we cannot approve your proposed CSF of December 20, 2006, even if we extended the PRIA date to allow you sufficient time to submit revised, acceptable spray pattern data. Therefore, we are requesting that you withdraw this proposed amendment. An E-Mail to this effect, by July 5, 2007, would be appreciated.

Questions

If you have questions about this letter, please contact me at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock.dan@epa.gov (by E-Mail).

Sincerely yours,

Daniel B. Peacock, Biologist Insecticide-Rodenticide Branch Registration Division (7504C)

Enclosures: 1. Review of New Inert

2. Conclusions - Efficacy Review of Spray Pattern/Spray Duration Tests

Dan Peacock, Flash Drive, 2gb, P:\Documents\Word, WP, Excel, etc\Capsaicin\55541-2, new CSF, new inert, 6-25-2007.doc



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON D.C., 20460

OFFICEOF
PREVENTION PESTICIDES AND
TOXIC SUBSTANCES

DP Barcodes: 336501

MEMORANDUM

DATE: April 26, 2007

SUBJECT: CSF Amendment: Non-food inert ingredients in Counter Assault Bear

Deterrent (EPA Reg. No. 55541-2)

FROM: TracyH Ward, Biologist Macu Ward 4/26/07

Inert Ingredient Assessment Branda Registration Division (7505P)

THRU: Pauline Wagner, Branch Chief Queline Wagner 4/30/07

Inert Ingredient Assessment Branch Registration Division (7505P)

TO: Dan Peacock

Insecticide-Rodenticide Branch Registration Division (7505P)

Summary:

Dan Peacock of the Insecticide-Rodenticide Branch requested that IIAB review the math of the CSF, the acceptability of the alternate CSF, and the acceptability of the new, non-food use of the inert ingredients

as a carrier, and propellant in Counter Assault Bear Deterrent (EPA Reg. No. 55541-2).

IIAB reviewed the CSF for the acceptability of the inert ingredients

The proposed propellant, is approved for non-food use. However, we are not able to approve the requested use of the currently available information. We have toxicity concerns about (including mammalian toxicity and high aquatic toxicity) and this chemical may be persistent in the environment. The proposed alternate CSF for Reg. No. 55541-2 is not acceptable as amended.





Dan Peacock/DC/USEPA/US 07/09/2007 12:58 PM To Pauline Wagner/DC/USEPA/US@EPA

cc John Hebert/DC/USEPA/US@EPA

bcc

Subject Fw: Counter Assault EPA #55541-2

Pauline,

I am forwarding this E-Mail that I received from Cristina Griffin, agent for the company.

 I have already informed Ms. Griffin that she has the complete review and that we, at present, approve new, non-food inerts for all uses, not just the one requested.

If you have some standard language that I could provide the agent this afternoon, that would be great.

Thank You,

Daniel B. Peacock, Biologist

Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

- Forwarded by Dan Peacock/DC/USEPA/US on 07/09/2007 12:53 PM -



"Cristina Griffin" <cgriffin@delta-ac.com> 07/09/2007 12:54 PM

To Dan Peacock/DC/USEPA/US@EPA

cc John Hebert/DC/USEPA/US@EPA, "Pride Johnson" <pri>pride@counterassault.com>

Subject Counter Assault EPA #55541-2

Dan.

As we discussed, we have received your letter of July 2, 2007 regarding the proposed inert ingredient and revised CSF. Counter Assault requests a 60 day extension of the PRIA date for a decision on the proposed alternate CSF. We also request additional information as discussed below.

1) The inert ingredient data review we received does not seem to be complete. We request a review that explains EPA's rationale for its conclusions, i.e., how EPA derived its conclusions based on the data, or what data EPA would need to address its concerns.

The first page summary, second paragraph, states: "However, we are not able to approve the requested use of [inert ingredient] based on the currently available information. We have toxicity concerns about [inert ingredient] (including mammalian toxicity and high aquatic toxicity) and this chemical may be persistent in the environment." The two pages following the statement provide a summary of the ingredient information we sent, but do not provide any explanation regarding how the conclusion was reached. In at least one area, the summary appears to contradict information in another section of EPA's memo: The summary notes a high aquatic toxicity, but the information under "Fate" on page three of the data review memo states "Therefore, not a significant threat to aquatic or terrestrial environments." Therefore it is crucial for EPA to provide the entire review, including derivation of all of its conclusions, so Counter Assault can understand the full scope of the issues and whether additional information can be provided to address issues.

2) As you know, the bear spray use is limited in comparison to other uses of pesticide products. We believe that the concerns about the proposed ingredient may be less about its use in this specific bear repellent than about use in other more conventional pesticide products. We understand that typically when EPA approves an inert, this allows any pesticide product to include the approved inert. However, we would like to explore with the Agency whether there may be a mechanism for approving this ingredient for only limited uses. As you know, the purpose of making this change is to comply with VOC regulations that are being increasingly promulgated in the States. In addition, it is clear that only ingredients with certain characteristics can be used in bear repellent sprays because of the nature of the product.

Conclusion

Once we have resolved issues regarding the inert ingredient, we will address the issues regarding the spray data by conducting another study addressing EPA comments. Please send me a confirmation of the deadline extension, the additional inert data review pages, and any information on next steps.

Thank you for your help.

Best Regards, Cristina Griffin Delta Analytical Corp.

e-mail: cgriffin@delta-ac.com

voice: 301-680-7971 fax: 301-680-7975

12510 Prosperity Drive, Suite 160

Silver Spring MD 20904



Dan Peacock/DC/USEPA/US 07/09/2007 11:47 AM To John Hebert/DC/USEPA/US@EPA

CC

bcc

Subject 55541-2, Bear Deterrent, New CSF with New, Non-Food Use, and New Spray Pattern

Data

Status of Split Action (305, new, nonfood inert and R34, Spray Pattern), Due Date: July

11, 2007

John,

Status:

Here is the status of this action, due July 11, that I am working with the agent to withdraw today, if possible.

- The new, non-food inert was not approved (305).
- The Spray Pattern data (R34) were not acceptable.
- We can do no more work on this action.

Agent Questions:

Cristina Griffin of Delta Analytical had some basic questions that she will put into an E-Mail and that I will try to address today, with Pauline's help, before deciding to withdraw or to request an extension.

Note:

- Tomorrow I am on sick leave because I have to admit my mother-in-law into the hospital so my time to spend on this action will be more limited.
- . I will keep you informed in case you or Meredith has to talk to the agent

Thank You,

Daniel B. Peacock, Biologist Tel: 703-305-5407

Fax: 703-305-6920

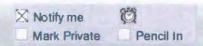
E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202





When Ends Thu 07/19/2007 02:00 PM Where RD Small Conference Room E	Subject	Company Request to Reconsider Decision No. Inert in Counter Assault Bear Deterrent, 555				Dan Peacock/DC/USEPA/US			
John Hebert/DC/USEPA/US@EPA, Karen Angulo/DC/USEPA/US@EPA, Kerry Leifer/DC/USEPA/US@EPA, Pauline Categorize Categorize	When	Ends Thu 07/19/2007 02:00 PM					Reserved	The following have been requested RD Small Conference Room E (S-7791)/Potomac Yard One @EPA	
Optional (cc) Bill Jacobs/DC/USEPA/US@EPA	Invitees	Invited The following invitees he John Hebert/DC/USEPA Required (to) Angulo/DC/USEPA/US®			rt/DC/USEPA/ /USEPA/US@	US@EPA, Karen EPA, Kerry	Categoriz	e	
Scheduler Click to see Invitee status		Optional (cc) Bill Jacobs/DC/USEPA/US@EPA Dip Click to see Invitee status				S@EPA		_/	

- Cristina Griffin, agent to Counter Assault, and Pride Johnson, President of Counter Assault have requested this meeting to request EPA to reconsider their decision not to allow a new inert in this product.
- They will explain their position at the meeting, and EPA will explain their position.
- Ms. Griffin will be physically present, and Mr. Johnson will join us by phone.
- Ms. Griffin has promised to outline their position in a document and supply it no later than Monday, July 16, COB. When it arrives, I will forward it to meeting
- Their major points are 1) that EPA should consider exposure in its assessment for new, non-food inerts and 2) that EPA should consider that the Air and Radiation Program permits the new inert as a substitute for the one currently in their product.

My phone is 703-305-5407 if there are questions.

with phone

Page 26 of 26

Cristina Griffin	301 680	July 9, 2007	55541 2	Will send E-Mail for these pts:	7/9/2007,
Delta	7971 or73	9:24AM	Due 7 11-2007	Did they get entire review? Yes	11AM
De Ita Bhalytica			Needs to talk.	2. Can they approve it for just this use? No 3. What was there rationale for disapproval? Persistence, high mammalian tox, high aquatic tox Cristina will send me an E-Mail. Did not want to withdraw.	
Wheel	: Poti	inle,		I talked to Pauline Wagner, Branch Chief of the Inert Ingredient Assessment Branch (IIAB), who confirmed the information that I had previously given to the agent. The key test of concern was the 2 generation reproduction study where there were liver effects as low as 5mg/kg/day. They should select another carrier with a NOAEL level of 50 mg/kg/da or higher and without severe effects as the lowest effect level. We would be willing to have a meeting to discuss the matter further and help them select another carrier. I asked the agent to discuss the situation with the company and send me and John Hebert	July 9, 2007 4:40PM

Dan Peacock, Flash Drive 1gb, E:\Tracking\Phone and Other\Word\2007 Phone Calls.doc



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

FAX COVER

To: Cristina Griffin Date: 7/2/2007
Recipient Fax Number: 3ch 680 - 7975
From: Daniel Peacock Phone: 703 305-5407
Return Fax Number: 763 308 - 662 9
Number of Pages (including cover sheet) (3)

COMMENTS: unacceptable	0
1) We found ouse of new, non-factinent inerty	
2) We found problems with the efficacy (spray pattern data)	
3) there is no more work that we	
4) We would appreciate an Email withdrawing this amendment as a particular of this artion was given a PRIA code 1226 to Denviron	



Dan Peacock/DC/USEPA/US 07/02/2007 03:30 PM

To John Hebert/DC/USEPA/US@EPA

CC

bcc

Subject Fw: E-Mail Copy of Letter and Request to Withdraw Amendment Application

John,

I talked to Jeff Jones of Delta Analytical late today.

If they don't get the letter and reviews by Tues, they will arrange to have a messenger pick up the package Thursday morning so that they can
cut on our request to withdraw the amendment.

Thank You,

Daniel B. Peacock, Biologist Tel: 703-305-5407 Fax: 703-305-6920 E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

--- Forwarded by Dan Peacock/DC/USEPA/US on 07/02/2007 03:29 PM ---



Dan Peacock/DC/USEPA/US

07/02/2007 03:21 PM

To cgriffin@delta-ac.com

cc John Hebert/DC/USEPA/US@EPA

Subject E-Mail Copy of Letter and Request to Withdraw Amendment Application

Dear Cristina,

I regret to inform you that your request for an new, non-food inert was unacceptable.



To cgriffin@delta-ac.com

cc John Hebert/DC/USEPA/US@EPA

pcc

Subject E-Mail Copy of Letter and Request to Withdraw Amendment Application

Dear Cristina,

I regret to inform you that your request for an new, non-food inert was unacceptable.

In addition, we found problems with the spray pattern data.

For the above reason, there is no more work that we can perform with this amendment.

 Because we performed a portion of this review under PRIA Code R34, I am requesting that you withdraw this amendment by E-Mail, preferably by this Thursday, July 5.

Attached is a copy of my letter.

If you have questions, please contact me.



55541-2, new CSF, new inert, 6-25-2007.doc

Thank You,

Daniel B. Peacock, Biologist Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

305 5-803017 1130 R-34 5-806184

July 2, 2007

Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904

Attention: Ms. Cristina Griffin

Subject: Counter Assault Bear Deterrent

EPA Reg. No. 55541-2

Your amended application of December 20, 2006

Your resubmission of February 27, 2007 Request to Withdraw Amendment

Purpose The purpose of this submission, under section 3 of the Federal Insecticide,

Fungicide, and Rodenticide Act (FIFRA), is to replace your existing Confidential Statements of Formula (CSF), November 24, 2003, and March 16, 2006, with a new CSF, dated December 20, 2006, including a new inert ingredient not found in any currently registered product.

Review A. New Non-Food Inert

We have reviewed the data package on the new inert (no MRID assigned) and the new spray pattern data (MRID No. 470668-01) to support this amendment.

Based on the information provided, we are not able to approve the requested use of the new, non-food inert and its associated CSF. We have concerns about the mammalian and aquatic toxicity of the ingredient. We have attached a copy of our review.

B. Spray Pattern Data

 The report lacks sufficient detail to assess spray pattern. It was not clear how the authors determined spray distances. Also, the study lacked data on spray pattern dimensions.

- 2. For the spray durations for the 230g (8.1 oz) canisters, the most that could be claimed would be "approximately 6 seconds" for this size of container. There was no specific test for the 290g (10.2 oz) canisters.
- You will find additional details in the conclusions of our review of this study in the Enclosure 2, which will assist you if you run such tests in the future.
- 4. The spray duration claims should be changed to "approximately 7 seconds" for the 8.1g container and "approximately 9 seconds" for the 10.2g container. Those times approximate the minimum times that were reported for containers of those sizes for the basic formulation of this product.

Request to Withdraw Because we cannot approve the new, non-food inert, we cannot approve your proposed CSF of December 20, 2006, even if we extended the PRIA date to allow you sufficient time to submit revised, acceptable spray pattern data. Therefore, we are requesting that you withdraw this proposed amendment. An E-Mail to this effect, by July 5, 2007, would be appreciated.

Questions

If you have questions about this letter, please contact me at 703-305-5407 (by phone), 703-305-6596 (by fax), or peacock,dan@epa.gov (by E-Mail).

Sincerely yours,

Daniel B. Peacock, Biologist Insecticide-Rodenticide Branch Registration Division (7504C)

Enclosures: 1. Review of New Inert

2. Conclusions - Efficacy Review of Spray Pattern/Spray Duration Tests

Dan Peacock, Flash Drive, 2gb, P:\Documents\Word, WP, Excel, etc\Capsaicin\55541-2, new CSF, new inert, 6-25-2007.doc

55591-2

Page 231: *Inert ingredient information may be entitled to confidential treatment*

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TracyH Ward/DC/USEPA/US

04/20/2007 10:37 AM

To Dan Peacock/DC/USEPA/US@EPA, Pauline Wagner/DC/USEPA/US@EPA

Mary Frankenberry/DC/USEPA/US@EPA

bcc

Subject Inert Ingredient

Dan,

After further discussion with OGC's Michele Knorr-we've found that it would not be practical to try limiting for non-food uses. Because it is highly toxic to aquatic organisms and persistant in the environment, we cannot make the FIFRA safety findings for the use of this chemical as a non-food use inert ingredient.

Please contact me if you have any questions. I'll return the data package to you and close the bean in OPPIN.

Thank you,

TracyH Ward, Biologist Inert Ingredient Assessment Branch EPA/OPPTS/OPP/Registration Division (7505P) Phone: (703) 308-9361



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON D.C., 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DP Barcodes: 336501

MEMORANDUM

DATE: April 26, 2007

SUBJECT:

CSF Amendment: Non-food inert ingredients in Counter Assault Bear

Deterrent (EPA Reg. No. 55541-2)

FROM:

TracyH Ward, Biologist

Tracy Ward 4/26/07

Inert Ingredient Assessment Branch

Registration Division (7505P)

THRU:

Cauline Wagner 4/30/07 Pauline Wagner, Branch Chief

Inert Ingredient Assessment Branch

Registration Division (7505P)

TO:

Dan Peacock

Insecticide-Rodenticide Branch Registration Division (7505P)

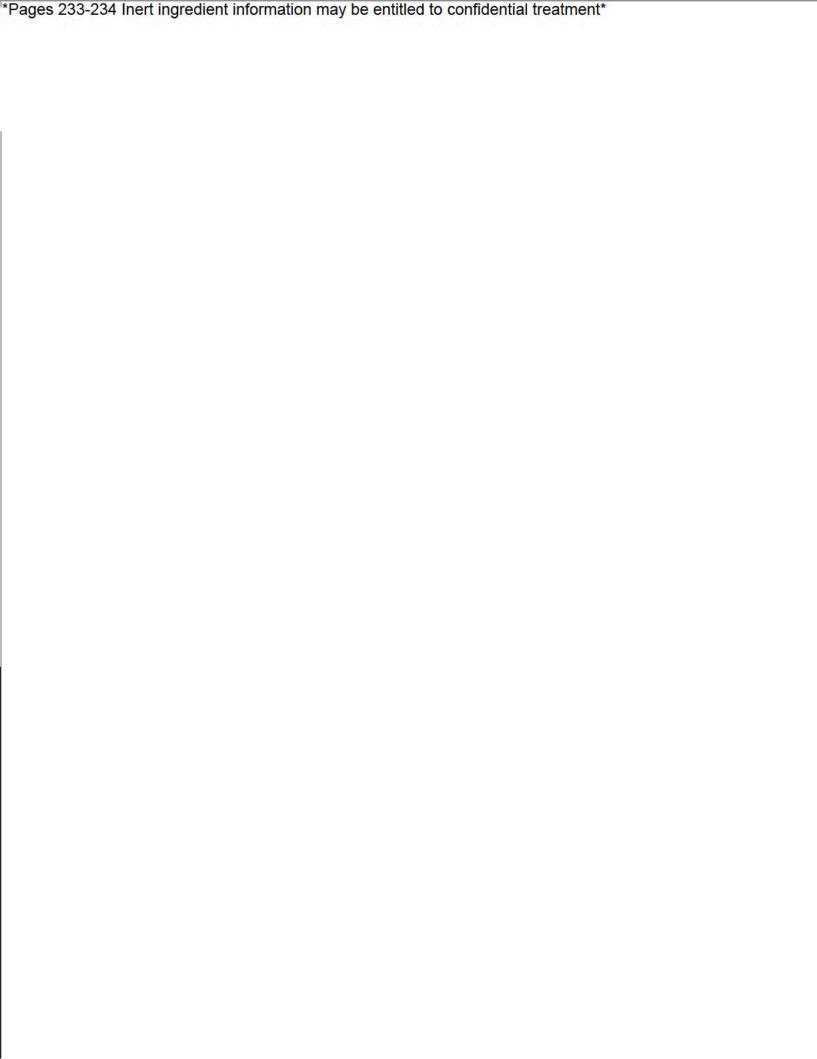
Summary:

Dan Peacock of the Insecticide-Rodenticide Branch requested that IIAB review the math of the CSF, the acceptability of the alternate CSF, and the acceptability of the new, non-food use of the inert ingredients

as a carrier, and propellant in Counter Assault Bear Deterrent (EPA Reg. No. 55541-2). as a

IIAB reviewed the CSF for the acceptability of the inert ingredients

The proposed propellant, is approved for nonfood use. However, we are not able to approve the requested use of based on the currently available information. We have toxicity concerns abou (including mammalian toxicity and high aquatic toxicity) and this chemical may be persistent in the environment. The proposed alternate CSF for Reg. No. 55541-2 is not acceptable as amended.







Decision #: 373589

DP #: (336501)

Date: 07-Feb-2007 Page 1 of 1

* * * Registration Information * * *

Registration:	55541-2 - COUNT	ER ASSAULT BEAR D	ETERRENT			
Company:	Company: 55541 - BUSHWACKER BACKPACK & SUPPLY CO.					
Risk Manager:	RM 07 - John Hebert -	(703) 308-6249 Room# PY1	S-7227			
Manager Reviewer.	Daniel Peacock DPEA	COCK				
Sent Date:		Calculated Due Date	e: 30-Jun-2007		Edited Due Date:	
ype of Registration:	Product Registration -	Section 3				
Action Desc	(305) DATA REQUIRE	D;TECHNICAL;				
Ingredients:	070701, Capsaicin(2%)				
*						
	**	* Data Package In	formation *	**		
Expedite:	○ Yes ● No	Date Ser	nt: 07-Feb-2007	37	Due Back:	
OP Ingredient:	070701, Capsaicin					
DP Title:		Label Included: Yes	No Pare	ent DP#:		
DP Title:	○ Yes ● No	Label Included: Yes	No Pare	ant DP#:		
DP Title: CSF Included: Assigned To	○ Yes ● No				Science Due Date:	31-Jan-2007
DP Title: CSF Included: Assigned To Organization: RD / III	○ Yes ● No			Last Possible S		
DP Title: CSF Induded:	○ Yes ● No		Date Out	Last Possible S	Science Due Date:	
DP Title: CSF Included: Assigned To Organization: RD / II Team Name:	○ Yes ● No		Date Out	Last Possible S	Science Due Date:	
DP Title: CSF Included: Assigned To Organization: RD / II Team Name:	Yes No		Date Out	Last Possible S	Science Due Date:	
DP Title: CSF Included: Assigned To Organization: RD / II Team Name:	Yes No	Date In	Date Out	Last Possible S	Science Due Date:	
DP Title: CSF Included: Assigned To Organization: RD / II Team Name:	Yes No	Date In Studies Sent for R	Date Out	Last Possible S Sub Data P	Science Due Date:	

Dear Chemist:

Purpose:

Please review the chemistry portion of this amendment dated 12-20-2006 to have an alternate CSF, changes that also require efficacy data. The Co wants to substitute the carrier (new, nonfood inert) and the propellant.

Please review the math of the CSF, the acceptability of the alternate CSF, and the acceptability of the new, nonfood inert and propellant.

* * * Data Package Instructions * * *

Action Codes and Due Dates

- 1. Chemistry, 305, >90 Days
- 2. Efficacy, R34, 4 Months, to be set up after data received.

Contents:

1. Application

- 2. Cover retter
 3. Chemistry Information (no MRIDs)
 4. @Id CSF (dated 3-16-2006)
 5. New CSF (dated 12-20-2006)
 6. E-Mail (2-7-2007)

Questions:

Please contact me if you have any questions.

Dan Peacock, 305-5407

IRB EFFICACY REVIEW

DP Number(s)

339786

IN: 5/10/07 OUT: 6/05/07

PRODUCT NO.: 55541-2

DATE RECEIVED BY OPP: 2/28/07

DATE OF SUBMISSION: 2/27/07

DATE SUBMISSION ACCEPTED: 5/10/07

TYPE OF PRODUCT: Animal-attack Repellent

DATA MRID or ACCESSION NOS.: 470668-01

PRODUCT MANAGER NO.: 07

PRODUCT NAME: COUNTER ASSAULT BEAR DETERRENT

COMPANY NAME: Bushwacker Backpack & Supply Co., Inc. ("dba COUNTER ASSAULT")

SUBMISSION PURPOSE: Document spray time and pattern for proposed alternate

formulation

CHEMICAL & FORMULATION: 2.0% Capsaicin and related capsaicinoids aerosol

Efficacy Review: COUNTER ASSAULT BEAR DETERRENT, 55541-2

Bushwacker Backpack & Supply Co., Inc. (a.k.a. "dba COUNTER ASSAULT")

Kalispel, MT 59901

200.0 INTRODUCTION

THIS REVIEW DISCUSSES CONFIDENTIAL BUSINESS INFORMATION (CBI). DO NOT DISCLOSE CBI TO UNAUTHORIZED THIRD PARTIES OR TO ANYONE LACKING APPROPRIATE CLEARANCES. THIS REVIEW DISCUSSES AN INERT INGREDIENT THAT IS NOT MANUFACTURED BY THE REGISTRANT OR THE REGISTRANT'S AGENT. CONSEQUENTLY, THOSE ENTITIES MAY BE UNAUTHORIZED THIRD PARTIES WITH RESPECT TO SOME INFORMATION DISCUSSED HERE.

200.1 Uses

55541-2 is a 1.73% Capsaicin (0.71%) and Other Capsaicinoids (1.02%) aerosol Federally registered for use at unspecified sites

only to deter bears which are attacking or appear likely to attack humans.

200.2 Background Information

See efficacy reviews of 1/5/98, 1/26/99, 4/22/99, 8/6/99, 7/14/00, 9/5/00, 9/21/00, 12/28/00, 12/7/01, 7/2/01, 6/29/04, and 8/1/05, along with other information in the two-volume registration jacket for 55541-2. See also the enforcement case review of 9/9/05 for FY05-VIII-005. Note discussions of claims made in labeling and advertising for this product and other bear pepper sprays. Note especially discussions of previously submitted spray pattern studies in efficacy reviews of 1/5/98 and 6/29/04. 55541-2 was registered on 5/12/98 as the first U.S. registration for Capsaicin-containing bear repellent. Such products were sold illegally in the U.S. prior to that time. The current labeling for 55541-2 was "ACCEPTED with COMMENTS" on 11/22/04.

This review discusses issues related to an alternate formulation proposed for this product. The items that I received to review include:

- a letter of 12/20/06 from Christina Griffin of Delta Analytical Corporation, Silver Spring, MD, jointly to the Registration Division's (RD's) Inert Ingredient Assessment Branch (IIAB) and RD's Insecticide-Rodenticide Branch (IRB) "requesting approval of a non food use inert ingredient";
- a completed registration amendment application form dated "December 20, 2006" and signed by Griffin;
- a completed Confidential Statement of Formula (CSF) for an "Alternative Formulation" dated "3/16/06" and bearing an illegible signature from someone (apparently Connie B. Welch) with the title of "Global Regulatory Consultant, Authorized Agent for Counter Assault";

- a completed Confidential Statement of Formula (CSF) for an "Alternative Formulation #2" dated "12/20/06", bearing Griffin's signature, and identifying her as "Agent, Counter Assault";
- a "MEMORANDUM" of 2/2/07 entitled "Need to Assign Different OPPIN Codes for Actions to Add New, Non-Food Inerts" from Daniel Peacock of IRB to Meredith Laws, Chief of IRB;
- an "E-Mail Message" of 2/2/07 summarizing a meeting involving certain IRB
 personnel regarding the appropriate OPPIN code to use for the submission of
 12/20/06 and the span of calendar time that should be allotted for its review and
 completion.
- two distinct letters of 2/27/07 to IRB from Griffin;
- a completed registration amendment application form dated "February 27, 2007" and signed by Griffin;
- 9. an e-mail note dated "04/20/07" from Tracy H. Ward of IIAB to Peacock (and others) regarding "Inert Ingredient
- a "<u>MEMORANDUM</u>" of 4/26/07 from Ward to Peacock which amounts to a review of the registrant's request for inert-ingredient clearance(s);
- a "DATA PACKAGE BEAN SHEET" of "10-May-2007" sent by Peacock to me regarding certain matters pending for 55541-2; and
- 12. a report of a "Spray Pattern" study.

According to Griffin's letter of 12/20/06, Bushwacker/COUNTER ASSAULT seeks an alternative formulation using

as "a carrier" in 55541-2. By all accounts included in the efficacy review package, that substance has not been cleared as an inert ingredient for use in pesticides in the U.S. The rationale behind the request appears below, quoted from Griffin's letter of 12/20/06.

As the State of California and other areas have begun to limit volatile organic compounds (VOCs) in pesticides and other products, Counter Assault has been searching for an ingredient that does not contain VOCs and still works well in the formulation. EPA's Office of Air and Radiation has excluded from the definition of VOC "on the basis that these compounds have negligible contribution to tropospheric ozone formation" (see tab #1 in the enclosure). Counter Assault has found that the carrier works well as a replacement for the current carrier in its bear deterrent formulation and wants EPA approval to use the ingredient in its registered product.

The spray pattern report evidently was submitted along with the longer of Griffin's letters of 2/27/07. The submission of that item is the primary reason why these materials were routed for an efficacy review. However, the "DATA PACKAGE BEAN SHEET" of "10-May-2007" references the other documents listed above and notes that the proposed inert-ingredient clearance was not approved by IIAB ("a position that they have verified with OGC" — EPA's Office of General Counsel). The disapproval occurred for reasons apparently unrelated to 55541-2 "but from other uses [of the inert] that could result from its approval in this product". Although there is authority to approve inert ingredients only for "non-food" uses, there is no clear authority for such clearances to be made on a use-by-use basis (and probably no way to ensure that an inert ingredient cleared for one non-food use would be flagged if proposed for another non-food use for which it had not been cleared). On the "DATA PACKAGE BEAN SHEET" of "10-May-2007", I am instructed to "still review these Spray Pattern Data because the above policy could change."

Bear pepper sprays are to be used protect humans in what may literally be life-or-death situations. Successful use of a bear pepper spray typically would spare the human and the bear from significant long-term adverse health consequences. The nature of the spray pattern delivered by a container of bear pepper spray is integral to the product's utility, as are the distance over which an effective spray cloud travels and the duration (in seconds) of availability of a useful spray pattern.

Claims as to spray distance and effective spraying time also have been featured in promotional battles between registrants of bear pepper sprays. As is chronicled in the registration jacket for this product, Bushwhacker/Counter Assault has been a protagonist in some battles. Such battles have been fairly frequent and often have involved EPA, informally and formally, as with the enforcement case FY05-VIII-005 and several other matters.

In its most immediately relevant part, §2(q) of FIFRA defines "MISBRANDED" as

(1) A pesticide is misbranded if-

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;...

In <u>40 CFR</u> §156.10(a)(5), the Code of Federal Regulations provides examples of types of statements which categorically are regarded as "false or misleading". These categories (quoted immediately below) are indicated in <u>40 CFR</u> §156.10(a)(5)(I) through (x).

- (i) A false or misleading statement concerning the composition of the product;
- (ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
- (iii) A false or misleading statement concerning the value of the product for purposes other than as a pesticide or device;
 - (iv) A false or misleading comparison with other pesticides or devices;

- (v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government:
- (vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;
- (vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;
- (viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations.
- (ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans or pets" with or without such a qualifying phrase as "when used as directed"; and
- (x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:
 - (A) "Contains all natural ingredients";
 - (B) "Among the least toxic chemicals known"
 - (C) "Pollution approved".

Of the 10 categories of "false or misleading" statements listed under <u>40 CFR</u> §156.10(a)(5), items "(ii)" and "(iv)", effectiveness and inter-product comparisons, are most relevant to the results of spray pattern tests.

201.0 DATA SUMMARY

201.1 Formulations

The CSF dated "3/16/06" is stamped "APPROVED 9/13/06 SM", signed by "Paul J Mastradone", and hand-marked "last approved SF 3-16-2006". That CSF is for an "Alternative Formulation". The "Basic" CSF for 55541-2 seems to be the one dated 11/24/03, which IRB accepted on 7/8/04. Accepting that CSF increased the nominal concentration of Capsaicin and related capsaicinoids in 55541-2 from 1.73% (CSF of 3/4/98) to 2.0%. The CSFs of 11/24/03 and 3/16/06 both appear to be current. They describe formulations that are very similar but differ with respect to suppliers of Oleoresin Capsicum – the source of active ingredients – and have compensatory differences in the concentrations of the inert ingredients claimed. The source listed on the CSF of 3/16/06 apparently is slightly "hotter" than the source claimed on the CSF of 11/24/03.

The proposed "Alternate Formulation #2" dated "12/20/06" corresponds to the "Alternative Formulation" of "3/16/06" in name, supplier, and concentration of the active ingredient, and in name but not concentration (and not supplier in one case) for two of the four remaining ingredients. Where is listed as a "propellant" on the "Alternate Formulation" of 3/16/06,

"Carrier" components, the "Alternative Formulation #2" of 12/20/06. As one of two

aforementioned	where the "Alternate
Formulation" shows	and describes it as
T	he inert ingredients claimed for the "Alternative Formulation" on
the CSF of 3/16/06 corre 11/24/03.	spond in name to those claimed on the "Basic" CSF of

In her "MEMORANDUM" of 4/26/07, Ward notes that the propellant cleared as an inert ingredient for non-food uses. However must be a supported by the support of the support

toxicity concerns about including mammalian toxicity and high aquatic toxicity) and this chemical may be persistent in the environment.

In the event that this interpretation or the policy of not allowing use-by-use clearances for inert ingredients is changed, I will review the spray pattern test report, as was requested.

201.2 Efficacy Data

The spray pattern test report is cited and discussed below.

Griffin, C. and Johnson, P. (2007) Counter Assault Bear Deterrent EPA Reg. No. 55541-2 spray pattern. Unpublished report, Bushwacker Backpack and Supply Co., Inc. DBA Counter Assault, Kalispel, MT, and Delta Analytical Corporation, Inc., Silver Spring, MD, 5 pp. plus 4-page "CONFIDENTIAL APPENDIX".

MRID# 470668-01

This report is dated "February 21 2007" Thus it was completed between the application for clearance of and the submission of 2/27/07. However, the report's "**Procedure**" paragraph, quoted in its entirety below, states that the trial was run on 9/11/06.

On September 11, 2006, Pride Johnson (Chemist) and Counter Assault employees conducted a study to verify the spray distance and spray duration (time) over which Counter Assault Bear Deterrent (AF) 230 grams travels. The study was conducted using twelve (12) laboratory-formulated samples sprayed outdoors in a small clearing in a heavily wooded area at approximately 9:30 AM with virtually no wind at approximately 75EF. In order to standardize the spray distance and pattern, distances of 26 to 34 feet were measured in 2 foot increments. Several cans of the Basic were sprayed and the spray distance and pattern were visually monitored. Next the AF was sprayed and the distance was compared to the spray distance of the Basic. Alternating the Basic spray time and distance with the AF spray time and distance provided a good comparison of the two. Subsequently, the AF was sprayed to establish the spray distance and the AF spray distance was recorded; the spray duration was recorded using a stopwatch.

As no raw data sheets accompany the Griffin and Johnson (2007) report, it is not

possible to determine whether the time of testing and the ambient temperature were recorded at any phase of the trials. As the trials could not have been completed instantaneously, a start time and a finish time should have been recorded at the very least. The ambient temperature probably changed somewhat over the course of time taken to complete the testing. Wind speed and direction should have been measured right before each individual canister was tested.

Spray distances ranging from 26 to 34 feet were reported for the 12 "AF of 230 grams" units tested. Each of these results was compared to the 30-foot distance listed on the "Basic Label (230g)", with 6 test canisters reportedly exceeding that distance, 4 equaling it, 2 falling short of it (by 2 and 4 feet). The "average" spray distance for the "AF of 230 Grams" was reported to be "31 feet", slightly farther than the "30 feet" claimed for the "Basic Label (230g)".

Spray durations ranging from 5.97 to 9.07 seconds were reported for the 12 "AF of 230 grams" test units. The reported "Average AF (230g)" spray time is "7.7 seconds", slightly more than the "7.2 seconds" reported for the "Basic Label (230g)".

Griffin and Johnson (2007) report no tests of the larger (290-g) Counter Assault container with the ""AF" in it. Instead, the authors estimate what the spray distances and durations for such a container might be.

Since the spray distance is almost identical and the spray duration is within 0.5 seconds (acceptable variation in operating stopwatch), a mathematical correlation for the AF 290 can is:

AF 290/230 (7.68)= 9.7 seconds 290/230(31)= 39 feet Basic Label = 9.2 seconds = 32 feet

According to this thinking, the ratio of the net contents of the two containers is directly translatable into ratios of spray duration and spray distance. The assumed relationship for spray duration at least seems plausible, if the two containers have the same orifice shape and dimensions, but should be tested rather than assumed. That there is more material in the larger can does not clearly mean that the absolutely greater amount of propellants would move the also-increased amounts of other product components farther, let alone proportionately farther based on a ratio of the net contents of the two containers. The propellants have to move a greater mass of material out of a larger container.

A "CONFIDENTIAL APPENDIX" to the Griffin and Johnson (2007) report compares a "Basic Formula" to an "Alternate Formula #2" in several ways related to composition and physical properties. The to formulations reportedly are very similar to identical in vapor pressure although the "Basic Formula" is somewhat higher in bulk density and in percent of the total formulation that is comprised of propellants. The "CONFIDENTIAL APPENDIX" also notes that the two formulations differ with respect to one propellant but have another in common. The formulations also reportedly differ in "Carrier/Solvent" composition with "Alternate Formula #2" containing (the latter being

and "Basic Formula" containing

which the

7

^{*}Inert ingredient information may be entitled to confidential treatment*

"Alternate Formulation" of 3/16/06 also reports.

As noted above, bear pepper sprays are used in what often may be life-or-death situations. Consequently, projected spray times and distances have no place on the labels for such products. Average times and distances also have no place on such labels. Averages consider all observed values, which is more than Griffin and Johnson (2007) actually did. They discarded the maximum and minimum results and averaged the middle 10. What belongs on the label are minimum times and effective spray distances on which a user can rely.

The shortest reported spray time for the "AF of 230 Grams" is 5.97 seconds, which rounds to 6 seconds. That is the maximum spray duration claim that should be considered for the "Alternate Formulation #2" described by the CSF of 12/20/06, in the event that the other hurdles to its adoption are cleared. It also should be noted that 4 of the reported spray durations for the "AF of 230 Grams" were below 7 seconds, while 5 were above 8 seconds. That the individual times were not clustered around the "Average" suggest either that there was poor quality control among containers and/or their contents or a lack of consistency in the way the trials were timed.

The statement to the effect that a half-second difference is "acceptable variation in operating stopwatch" seems bogus to me. I have used stopwatches in timing behavioral events and athletic competitions, in the latter case usually with multiple watches and sometimes automatic timers as well. In such cases, discrepancies among timers as great as a full tenth of a second are very rare. I also have timed spray durations from videotaped tests of bear pepper sprays and generally have verified the accuracy of the times indicated in written reports of the same trials. It should be noted that spray times are to be measured from the onset of firing to the time when spray intensity begins to wane rather than on total "hiss" time. Due to the relatively large rectangular orifice on the container for a bear pepper spray products, it has been claimed that there is very little in the way of a fizzle hiss with such containers.

In tests run reportedly with the current "Basic" formulation (CSF of 11/24/03) for 55541-2, reported evacuation times for the 8.1-oz (230-g) container size rounded to or exceeded 7 seconds for all 5 cans, with one of the cans that were shaken before testing coming in at 6.96. A claim of approximately 7 seconds of spray time would be consistent with those data (see efficacy review of 6/29/04). However, IRB accepted a claim of ("approximately 7.2 seconds") without comment (label accepted on 11/22/04). The results for all 5 of the 230-g containers did average 7.2 seconds (see MRID# 461367 and efficacy review of 6/29/04). For the 290-g containers that reportedly had contained

In a telephone conversation of 6/28/04, Pride Johnson of Counter Assault told me that the high concentration of propellants and the nature of the canister's spray orifice likely contributed to his observation that there is very little terminal hiss time in the evacuation of containers of bear pepper spray. He stated that the spray times reported to be for the revised "Basic" CSF of 11/24/03 represented the span from the onset of spraying to when the containers no longer were delivering a meaningful amount of material. That conversation pertained to the report of a spray pattern test that was assigned MRID# 461367-04.

the formulation described by the CSF of 11/24/03, evacuation times ranged from 9.08 to 9.32 seconds, with the mean time having been 9.2 seconds.² Such results are consistent with a label claim of approximately 9 seconds of spray duration. IRB accepted a claim of "approximately...9.2 seconds" for the 290-g container. In the container evacuation trials reported for the CSF of 11/24/03, containers were weighed before and after testing to determined how much material had been expelled from them. In all cases (5 containers per size), the reported drop in mass either met (when rounded) or exceeded the net contents claimed for the container.

The shortest spray distance reported for the "AF of 230 grams" is 26 feet. That would seem to be the only distance that could be claimed for the "Alternate Formulation #2" described by the CSF of 12/20/06. However, it is not clear how that distance was determined. If it was a linear distance along a substrate, that figure would not likely compare accurately to the distances determined for other bear pepper spray formulations, including the distances determined in earlier trials of COUNTER ASSAULT formulations.

The spray distance is the distance from the canister over which an effective (i.e., bear-deterrent) pattern and amount of aerosolized Capsaicin and related capsaicinoids can be delivered. To determine such a distance, one must shoot the product toward a vertical target kept a fixed distance from the canister. One then examines the pattern of impingements on the target, measuring vertical and horizontal "diameters". In the initial spray pattern test (MRID# 443369-05) submitted for the product that became 55541-2, the product literally was shot at the side of a barn (see efficacy review of 1/5/98).³ In the

2 In accepting "with COMMENTS" labeling for 7/8/04, IRB instructed Counter Assault to use 7 seconds and 9 seconds as the spray duration claims for the 230-g and 290-g containers, respectively. One of the registrant's agents subsequently (9/23/04) requested that 0.2 seconds be added to the claims for both container sizes (i.e., to use the mean time rather than the minimum to set the claims). IRB acceded to the request on 11/22/04. For reasons indicated in this review and in others, I maintain that the minimum guaranteed time – preferably expressed in whole seconds – is all that should be allowed to be claimed. That the average time was increased by several slow cans or slow timers is of no use to a person holding a quick can while being confronted by one or more bears. The differences between the mean and quickest spray duration times were on the order of ¼ second or less for the rather well-behaved (n=5) data reported under MRID# 461367-04). However, Griffin and Johnson (2007) report spray times ranging from 5.97 to 9.07 seconds for 230-g canisters reportedly containing "Alternate Formulation #2" and, excluding both extreme results, calculate an average spraying time of "7.7 seconds" – 1.73 seconds greater than the shortest observed time. Personally, I would like to know if I were holding what might only be a 6-second can.

In the world of competitive promotion of bear pepper sprays, spray duration claims have become a big deal. That every fraction of a second "counts" in that arena probably is why the request of 9/23/04 was made on Counter Assault's behalf. Claiming 7.2 (or 7.7) seconds for a product with containers that might only hold 6 seconds of useful spray would be a "false or misleading" label statement.

³ In our telephone conversation of 6/28/04, Johnson told me that Bushwacker's President William Pounds had conducted those trials inside the barn. Johnson noted that he conducted his tests outdoors so as not to expose test personnel to airborne pepper spray in a confined space.

spray pattern trials reported (MRID# 461367-04) for the higher-strength formulation described by the CSF of 11/24/03, the target was an outside wall of an outbuilding (see efficacy review of 6/29/04). In both trial, spray diameters were reported. Spray diameters were measured on vertical targets which were inspected visually and by taste to determine whether material consistent with the product in appearance and/or pungency had impinged on the targets.

That different spray distances are reported for the various "AF of 230 Grams" containers used strongly suggests that distances were determined by a means other than use of a fixed vertical target. The Griffin and Johnson (2007) report does not discuss spray pattern diameters. That report also fails to mention vertical targets, let alone visual and taste assessments of them. Without use of a vertical target, data on spray pattern diameters would have been almost impossible to collect.

Taken at face value, the results reported by Griffin and Johnson (2007) are consistent with a claim of "approximately 6 seconds" for the formulation that they tested in 230-g containers. Taking Griffin and Johnson (2007) at their word regarding spray distance would limit the distance claim to 26 feet. As it seems unlikely that vertical targets were used, the data on which that claim would have to be based are suspect.

The primary Griffin and Johnson (2007) report ends with the "Conclusion" text quoted below.

The Test Parameters assumed that since the Bulk Density, the Percent of Propellant and Propellant's Vapor Pressure are very similar; [sic] the spray distance and spray duration would also be very similar. The study verified this hypothesis; the AF spray duration and distance are similar to, or exceed the Basic. However, Counter Assault wants the labeling on the formulated product with the AF to remain the same as labeling formulated with the Basic. Therefore, Counter Assault is not requesting changes to the current EPA approved labeling at this time.

At a future date if the Basic is eliminated and the AF becomes the only formula, Counter Assault may request an amendment to the labeling to reflect the results of this study as follows:

Size	Duration	Distance
230	7.5 seconds	31 feet
290	9.5 seconds	36 feet

For reasons discussed above, no distance claims are supported for the formulation described by the CSF of 12/20/06 in the 230-g canister and no claims of distance or duration were tested – much less supported – for the 290-g container. The minimum reported spray duration for "Alternate Formulation #2" was 5.97 seconds, consistent with a claim of "approximately 6 seconds". Consequently, acceptance of the CSF of 12/20/06 based on the spray data received thus far would require that the spray duration claimed on the label for the 8.1-oz container be shortened from "approximately 7.2 seconds" to "approximately 6 seconds" to accommodate all formulations that might be used for

55541-2. (If "Alternative Formulation #2" is not accepted, the duration claims should be changed to "approximately 7 seconds" and "approximately 9 seconds" for the 8.1-oz and 10.2-oz containers, respectively.) As for spray distance, we would have to choose between allowing the 30-foot claim to stand for all formulations in the 8.1-oz container or to reduce the claim to 26 feet based upon the lowest value reportedly observed for the most recently submitted alternate formulation.

As the inert ingredient was not cleared, discussions of label claims pertinent to the CSF of 12/20/06 may be postponed until such time, if any, that the ingredient is cleared.

The take-home message from this review should be that spray pattern tests must be conducted appropriately for their results to be useful. If trials are conducted outdoors, wind speeds and directions should be measured before each individual trial and should be verified as having been minimal. The person doing the spraying should be a measured fixed distance from a vertical target covered with a material (e.g. white paper or linen) that will readily show impacts of spray particles and that can be removed and replaced between succeeding trials. The distance between the sprayer and the target should be manipulated as an independent variable. Typically, that would be accomplished by moving the person closer or farther from the target rather than by moving the target. The vertical and horizontal dimensions of the pattern of impingement should be measured and reported to gauge the cross-sectional area of the spray cloud when it reaches the target. As Griffin and Johnson (2007) seem not to have performed the procedures appropriate for a spray pattern test, the most that should be taken from their report is the information regarding evacuation times for the 230-g container.

202.0 CONCLUSIONS

 The report of spray patterns and spray durations by Griffin and Johnson (2007, MRID No. 470668-01) lacks sufficient detail to be usable as a spray pattern study. It is not clear from the report how effective spray distances were determined, and no data on spray pattern dimensions are reported.

The information on spray durations for 230-g (8.1-oz) canisters included in the Griffin and Johnson (2007) report indicates considerable variation in spray times among containers and/or difficulties in the procedures used to determine spray times. As the minimum spray time reported (5.97 seconds) rounds to 6 seconds, the most that could be claimed based upon the reported test results is a minimum spray time of "approximately 6 seconds", which is lower than the claim that appears on the current accepted label for the 8.1-oz container of this product.

2. The Griffin and Johnson (2007) report does not describe testing of 290-g (10.2-oz) containers for spray characteristics. Rather, spray durations and distances reportedly were extrapolated for them using "average" results (minus highest and lowest values) for the 230-g container and assumptions of proportionality in spray duration and distance based upon the ratio of the net contents of the two containers and similarities in the physical properties of the proposed "Alternative Formulation #2" and the formulation that allegedly was used in prior tests. Using average scores

is not appropriate for values that are essentially to be guarantees. While a positive correlation contents and evacuation times seems likely to exist, it is not clear that there would be such a relationship for spray distances.

The spray duration and distance claims that Griffin and Johnson (2007) indicate in their "Conclusion" paragraphs that Counter Assault might want to make in the event that "the AF becomes the only formula" for 55541-2 do not track with the authors' data and projections from earlier in the report and would not be acceptable in any case based upon the nature and quality of their report.

Bear pepper sprays are used in what often may be life-or-death situations.
 Therefore, there is no room for error or exaggeration regarding information on spray durations or distances. The times and distances claimed should be minimums that can be expected reliably. Consequently, each container size and formulation must be tested for such properties.

Spray duration is to be timed from the onset of firing until the container ceases to deliver a cloud of material suitable for deterring bears, rather than from the onset of firing until nothing comes out of the container.

Spray pattern tests must be conducted appropriately for their results to be of value. If tests are conducted outdoors, wind speeds and directions should be measured for each individual trial and should be verified as having been minimal before the trial is attempted. The person doing the spraying should be a measured fixed distance from a vertical target covered with a material (e.g. white paper or linen) that will readily show impact of spray particles and that can be removed and replaced between succeeding trials. The distance between the sprayer and the target should be manipulated as an independent variable. Typically, that would be accomplished by moving the person closer or farther from the target rather than by moving the target. The vertical and horizontal dimensions of the pattern of impingement should be measured and reported to gauge the cross-sectional area of the spray cloud when it reaches the target.

4. Due to the rejection of as an ingredient for this product, its composition and labeling should remain consistent with the performance of the current accepted formulation(s). The spray distance claims should remain at 30 feet for the 8.1-g container and 32 feet for the 10.2-g container. The spray duration claims should be changed to "approximately 7 seconds" for the 8.1-g container and "approximately 9 seconds" for the 10.2-g container. Those times approximate the minimum times that were reported for containers of those sizes for the basic formulation of this product.

William W. Jacobs Biologist Insecticide-Rodenticide Branch June 5, 2007

DATA PACKAGE BEAN SHEET

Date: 10-May-2007 Page 1 of 2

Decision #: 376199

DP #: (339786)

PRIA Parent DP#:

* * * Registration Information * * *

	55541 - BUSHWACKE	R BACKPACK & SUPPLY	co .	
Risk Manager:	RM 07 - John Hebert - ((703) 308-6249 Room#PY	1 S-7227	
Manager Reviewer:	Daniel Peacock DPEA	СОСК		
Sent Date:		Calculated Due D	ate: 11-Jul-2007	Edited Due Date:
ype of Registration:	Product Registration - S	Section 3		
Action Desc:	(R34) NON-FAST-TRA	OK (INCLUDES CHANGE	S TO PRECAUTION	ARY LABEL STATEMEN
Ingredients:	070701, Capsaicin(2%))		
	* *	* Data Package I	nformation *	**
Expedite:	○ Yes ● No	Date S	Sent: 10-May-2007	Due Back:
DP Ingredient:	070701, Capsaidn			2
DP Title:				
		Label Included: Yes	No Pare	nt DP #:
	○ Yes ● No	Label Included: Yes	No Pare	nt DP #:
CSF Included:	Yes No			
CSF Included:	Yes No	Date In	Date Out	Last Possible Science Due Date: 11-Jun-2007
CSF Included: Assigned T Organization: RD / I	Yes No No RB Cy (IRB)	Date In	Date Out	Last Possible Science Due Date: 11-Jun-2007
CSF Included: Assigned T Organization: RD / I Team Name: Effica	Yes No No RB Cy (IRB)	Date In	Date Out	Last Possible Science Due Date: 11-Jun-2007
CSF Included: Assigned T Organization: RD / I Team Name: Effications viewer Name: Jacob	Yes No No RB Cy (IRB)	5/10/07	Date Out	Last Possible Science Due Date: 11-Jun-2007
CSF Included: Assigned T Organization: RD / I Team Name: Effications viewer Name: Jacob	Yes No No RB Cy (IRB)	5/10/07 Studies Sent for	Date Out (/5/07) Review ***	Last Possible Science Due Date: 11-Jun-2007
CSF Included: Assigned T Organization: RD / I Team Name: Effications viewer Name: Jacob	Yes No No RB Cy (IRB) ss, William	5/10/07 Studies Sent for Printed on Page 2	Date Out	Last Possible Science Due Date: 11-Jun-2007 Science Due Date: Sub Data Package Due Date:
CSF Included: Assigned T Organization: RD / I Team Name: Effications viewer Name: Jacob	Yes No No RB Cy (IRB) ss, William	5/10/07 Studies Sent for	Date Out	Last Possible Science Due Date: 11-Jun-2007 Science Due Date: Sub Data Package Due Date:
CSF Included: Assigned T Organization: RD / I Team Name: Effications viewer Name: Jacob	Yes No No RB Cy (IRB) ss, William	5/10/07 Studies Sent for Printed on Page 2	Date Out (/5/07) Review *** for this Decis	Last Possible Science Due Date: 11-Jun-2007 Science Due Date: Sub Data Package Due Date:

Request:

Please review the attached Spray Pattern Data (MRID No. 470668-01) that Bushwacker Backpack & Supply Co submitted to support their change in formula.

Background:

They changed two ingredients, a propellant and a solvent, which is a new, non-food inert. They are making the change in solvent because CA is proposing to phase out that solvent.

The Inerts Branch has not been able to approve the requested use of the new inert because of:

2.high aquatic toxicity, 3. persistance in the environment.

This Use and Other Uses:

The problem would not be from this use but from other uses that could result from its approval in this product. Currently IIAB are unable to approve inerts by use, a position that they have verified with OGC.

Effect of Disapproval of New Nonfood Use on Review of Spray Data

We should still review these Spray Pattern Data because the above policy could change.

Due Date:

The Due Date for this action is July 11, 2007.

Explanation for Timing of Review:

The reason that IIAB reviewed this action first was because, initially, the co did not submit the data in Dec 2006, only in February. We split the application into two parts:

- 1. review of new, non-food inert (305) and
- 2. review of spray pattern data (R-34).

List of Documents Sent:

I have enclosed the following documents for this request:

- 1. app form, Dec 20, 2006
- 2. cover ltr, Dec 20, 2006
- 3. asorted memos
- 4. app form, Feb 27, 2007
- 5. 2 cover ltrs, Feb 27, 2007
- 6. April 2, 2007 IIAB Summary of Data on New Inert
- 7. April 26, 2007 IIAB Memorandum not accepting New Inert
- 8. CSF, Current, March 16, 2006
- 9. CSF, Proposed, Dec 20, 2006
- 10. Spray Pattern Data (MRID No. 470668-01)

If you have questions, please contact me.

Dan Peacock, 305-5407

DP#: (339786)

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MRID Status

Page 2
*** Studies Sent for Review ***

Decision#: (376199)

Guideline

MRID 47066801

Griffin, C.; Johnson, P. (2007) Counter Assault Bear Deterrent EPA Reg. No. 55541-2 Spray Pattern 8.1 Ounce (230 grams) and 10.2 ounce (290 grams) Size. Unpublished study prepared by Bushwacker Backpack & Supply Co. 9 p.

Citation Reference



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

March 1, 2007

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OPP Decision Number: D-376199

EPA File Symbol or Registration Number: 55541-2

Product Name: COUNTER ASSAULT BEAR DETERRENT

EPA Receipt Date: 28-Feb-2007 EPA Company Number: 55541

Company Name: BUSHWACKER BACKPACK & SUPPLY CO.

KIRSTEN K. JOHNSON BUSHWACKER BACKPACK & SUPPLY CO. D/B/A COUNTER ASSAULT 120 INDUSTRIAL COURT KALISPELL, MT 59901

SUBJECT: Receipt of Amendment and 100% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application for amendment and 100% small business waiver request. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R34

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL STATEMENTS; SOURCE CHANGES TO AN UNREGISTERED SOURCE);

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If the determination indicates that payment is due, you will receive instructions for submitting payment at that time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 305-6249.

Front End Processing Staff

Sincerely

Information Technology & Resources Management Division

Fee for Service



This package includes the following

- New Registration
- Amendment
- ✓ Studies?
 ✓ Fee Waiver?
 - volpay % Reduction: ____

for Division	
O AD O BPPD	
• RD	
Risk Mgr.	7

Receipt No.

EPA File Symbol/Reg. No.

Pin-Punch Date:

S-806144

55541-2

2/28/2007

This item is NOT subject to FFS action.

Action Code:

Requested: R-34

Granted: R-34

Amount Due: \$ 3,150

Parent/Child Decisions:

Reviewer: Ryman

Date: 3-1-07

Remarks:

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Do not send the completed form to this address.		
Certification with Respe	ct to Citation	n of Data
Applicant's/Registrant's Name, Address, and Telephone Number Bushwacker Backpack & Supply Co., Inc., DBA Counter Assault c/o Delta Anal 12510 Prosperity Dr., Suite 160, Silver Spring, MD 20904, 301-680-7971	ytical Corp.	EPA Registration Number/File Symbol 55541-2
Active Ingredient(s) and/or representative test compound(s) Capsaicin and related capsaicinoids		Date February 27, 2007
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 1 Domestic outdoor	58)	Product Name Counter Assault Bear Deterrent
NOTE: If your product is a 100% repackaging or another purchased EPA-register submit this form. You must submit the Formulator's Exemption Statement (EPA		eled for all the same uses on your label, you do not need to
I am responding to a Data-Call-In Notice, and have included with this form should be used for this purpose).	form a list of con	npanies sent offers of compensation
SECTION I: METHOD OF DATA SUF	PORT (Check	k one method only)
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	the sele	ing the selective method of support (or cite-all option under ctive method), and have included with this form a t of data requirements (the Data Matrix form must be
SECTION II: GENERAL	L OFFER TO	PAY
I hereby offer and agree to pay compensation, to other persons, with re-		oraz orazo approatari, to are extent required by thirty
I certify that this application for registration, this form for reregistration, or this application for registration, the form for reregistration, or the Data-Call-In response method is indicated in Section I, this application is supported by all data in the Application or substantially similar product, or one or more of the ingredients in this under tha data requirements in effect on the date of approval of this application it similar composition and uses.	se. In addition, i gency's files that product; and (2)	If the cite-all option or cite-all option under the selective t (1) concern the properties or effects of this product or an) is a type of data that would be required to be submitted
I certify that for each exclusive use study cited in support of this registration of the written permission of the original data submitter to cite the study.	r reregistration,	that I am the original data submitter or that I have obtained
I certify that for each study cited in support of this registration or reregistration (b) I have obtained the permission of the original data submitter to use the study have expired for the study; (d) the study is in the public literature; or (e) I have no to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(f) and terms of compensation, if any, to be paid for the use of the study.	in support of thi	s application (c) all periods of eligibility for compensation the company that submitted the study and have offered (1)
I certify that in all instances where an offer of compensation is required, copie accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and	will be submitte	d to the Agency upon request. Should I fail to produce
such evidence to the Agency upon request, I understand that the Agency may init conformity with FIFRA.		

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		DATA MATRIX	(
Date February 27, 2007			EPA Reg No./File Symbol 55541-2	Page 1 of 4	
Applicant's/Registrant's Name & Ado	Iress Bushwacker Backpack & Supply Co., Inc., Di c/o Delta Analytical Corp. 12510 Prosperity Dr., Suite 160, Silver Spring	Product Counter Assault Bear Deterrent			
ngredient Capsaicin and related of	capsaicinoids				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY: Counter Assault Bear Deterrent					
830.1550	Product identity and composition	44336902	Bushwacker Backpack & Supply Co., Inc.	OWN	
830.1600	Description of materials used to produce the product	44336902	Bushwacker Backpack & Supply Co., Inc.	OWN	
830.1620	Description of production process	44336902	Bushwacker Backpack & Supply Co., Inc.	OWN	
330.1650	Description of formulation process	44336902	Bushwacker Backpack & Supply Co., inc.	OWN	
830.1670	Discussion of formation of impurities	44336902	Bushwacker Backpack & Supply Co., Inc.	OWN	
330.1700	Preliminary analysis	NA	NA	NA	
330.1750	Certified limits	See CSF	Bushwacker Backpack & Supply Co., Inc.	OWN	
330.1800	Enforcement analytical method	44336901	Bushwacker Backpack & Supply Co., inc.	OWN	
330.1900	Submittal of samples	NA.	NA	NA	
330.6302	Color	NA	NA	NA	
330.6303	Physical state	44336902	Bushwacker Backpack & Supply Co., Inc.	OWN	
330.6304	Odor	NA	NA	NA	
330.6313	Stability to normal and elevated temperature, metals, and metal ions	NA	NA	NA	
			Name and Title Cristina Griffin Agent for Bu and Supply Co., Inc.	shwacker Backpack	Date 2/27/07

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		DATA MATRI	K		
Date February 27, 2007			EPA Reg No./File Symbol 55541-2	Page 2 of 4	
Applicant's/Registrant's Name & Address Bushwacker Backpack & Supply Co., Inc., DBA Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Dr., Suite 160, Silver Spring, MD 20904		Product Counter Assault Bear Deterrent			
ngredient Capsaicin and related	capsalcinoids				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
330.6314	Oxidation/reduction: chemical incompatibility	NA	NA	NA	
330.6315	Flammability	44558301	Bushwacker Backpack & Supply Co., Inc.	OWN	
330.6316	Explodability	NA	NA	NA	
330.6317	Storage stability	NA	NA	NA	to be submitted
330.6319	Miscibility	NA	NA	NA	
330.6320	Corrosion characteristics	NA	NA	NA	to be submitted
330.6321	Dielectric breakdown voltage	NA	NA	NA	
330.7000	pH	NA	NA	NA	
330.7050	UV/visible absorption	NA	NA	NA	
330.7100	Viscosity	NA	NA	NA	
330.7200	Melting point/melting range	NA	NA	NA	
330.7220	Boiling point/boiling range	NA	NA	NA	
330.7300	Density/relative density/bulk density	44336902	Bushwacker Backpack & Supply Co., Inc.	OWN	
330.7370	Dissociation constant in water	NA	NA	NA	

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Form Approved OMB No. 2070-0060

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		DATA MATRIX	(
Date February 27, 2007			EPA Reg No./File Symbol 55541-2		Page 3 of 4
Applicant's/Registrant's Name & A	Address Bushwacker Backpack & Supply Co., Inc., DBA c/o Delta Analytical Corp. 12510 Prosperity Dr., Suite 160, Silver Spring, I		Product Counter Assault Bea		
ngredient Capsaicin and relate	d capsaicinoids				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7520	Particle size, fiber length, and diameter distribution	NA NA	NA	NA	
830.7550	Partition coefficient (n-octanol/water), shake flask method	NA NA	NA	NA	
830.7560	Partition coefficient (n-octanol/water), generator column method	NA	NA	NA	
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography	NA	NA	NA	
830.7840	Water solubility: column elution method; shake flask method	NA	NA	NA NA	
830.7850	Water solubility: generator column method	NA	NA	NA NA	
830.7950	Vapor pressure	NA .	NA	NA NA	
signature Q T & - [L-		Name and Title Cristina Griffin Agent for Bushwacker Backpack and Supply Co., Inc.		Date 2/27/07	

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DATA MATRIX			
Date February 27, 2007 Applicant's/Registrant's Name & Address Bushwacker Backpack & Supply Co., Inc., DBA Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Dr., Suite 160, Silver Spring, MD 20904			EPA Reg No./File Symbol 55541-2		Page 4 of 4
			Product Counter Assault Bear Deterrent		
Ingredient Capsaicin and relate	d capsaicinoids				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT PERFORMANCE					
96-1	Bear Deterrent	427676-06		OLD	
96-1	Bear Deterrent	00145063		OLD	
96-1	Bear Deterrent	Accession# 254706		OLD	
96-1	Bear Deterrent	Accession# 250625		OLD	
NA	Counter Asault Bear Deterrent: Spray Pattern 8.1 ounce and 10.2 ounce size	46136704	Bushwacker Backpack & Supply Co., Inc.	OWN	
NA	Counter Asault Bear Deterrent EPA Reg. No. 55541-2 Spray Pattern, 8.1 ounce (230 grams) and 10.2 ounce (290 grams) size	to be assigned	Bushwacker Backpack & Supply Co., Inc.	OWN	
TOXICITY	1				
870.2400	Primary Eye Irritation Study in Rabbits	46136702	Bushwacker Backpack & Supply Co., Inc.	OWN	
870.2500	Primary Skin Irritation Study in Rabbits	46136703	Bushwacker Backpack & Supply Co., Inc.	OWN	
Signature	2 11		Name and Title Cristina Criffin A sent for D	ushwarker Backnack	Date 2/27/07
Crestina,	5#		Name and Title Cristina Griffin Agent for Bushwacker Backpack and Supply Co., Inc.		258

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February 27, 2007

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive, Room S 4900
Arlington VA 22202

Attn: John Hebert, PM 7/ Dan Peacock, Insecticide Rodenticide Branch

Re: Application for Amendment with Data, Non fast track amendment, EPA # R34,

100% small business waiver requested

Product: Counter Assault Bear Deterrent

EPA Reg. No.: 55541-2

Company: Bushwacker Backpack and Supply Company, DBA Counter

Assault

Data Transmittal Letter Pursuant to FIFRA Section 3

Dear Mr. Hebert/Mr. Peacock:

On behalf of Bushwacker Backpack and Supply Company, DBA Counter Assault, I am submitting three copies of the following study in support of the amendment for the product Counter Assault Bear Deterrent, EPA Reg. No. 55541-2.

 Volume 1 of 1 Counter Assault Bear Deterrent EPA Reg. No. 55541 2 Spray Pattern 8.1 ounce (230 grams) and 10.2 ounce (290 gram) size

MRID#

If you have any questions regarding this submission, please call me at (301) 680-7971 or email cgriffin@delta-ac.com.

Sincerely,

Cristina Griffin
Agent for Counter Assault

cc: Pride Johnson, Counter Assault



February 27, 2007

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive, Room S 4900
Arlington VA 22202

Attn: John Hebert, PM 7/ Dan Peacock, Insecticide-Rodenticide Branch

Re: Application for Amendment with Data, Non fast track amendment, EPA # R34,

100% small business waiver requested

Product: Counter Assault Bear Deterrent

EPA Reg. No.: 55541-2

Company: Bushwacker Backpack and Supply Company, DBA Counter

Assault

Dear Mr. Hebert/Mr. Peacock:

On behalf of Bushwacker Backpack and Supply Company, DBA Counter Assault, we submitted a CSF amendment to EPA on 12/20/06. The amendment requested approval of an alternate formulation, and is under review. Dan Peacock requested that we submit the spray pattern study Counter Assault conducted in September 2006 on the new formulation. He indicated that the study should be submitted as a non fast track amendment under PRIA. The Spray Pattern study report is enclosed.

Bushwacker Backpack and Supply Company, DBA Counter Assault is a small business and qualifies for a 100% Small Business Waiver of the EPA fees for review of the amendment and studies. Enclosed is supporting documentation for the waiver request.

Enclosures:

- EPA form 8570 1
- Voluntary Small Business Certification Form for Pesticide Registration Fee Waiver/Reduction, and associated documentation
- Certification with Respect to Citation of Data form
- Data matrix

47086801 Volume 1 of 1, Counter Assault Bear Deterrent EPA Reg. Nφ. 55541-2 Spray Pattern 8.1 ounce (230 grams) and 10.2 ounce (290 gram) size

If you have any questions regarding this submission, please call me at (301) 680-7971 or email cgriffin@delta-ac.com.

Sincerely, .

Cristina Griffin
Agent for Counter Assault



United States

□ Registration

OPP Identifier Number S EPA **Environmental Protection Agency** X Amendment Washington, DC 20460 306451 □ Other Application for Pesticide - Section I 2. EPA Product Manager 3. Proposed Classification 1. Company/Product Number 55541-2 John Hebert/Dan Peacock ☐ Restricted □ None 4. Company/Product (Name) Bushwacker Backpack and Supply PM #7 Company, DBA Counter Assault /Counter Assault Bear Deterrent 5. Name and Address of Applicant (Include ZIP Code) 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my **Counter Assault** product is similar or identical in composition and labeling to: c/o Delta Analytical Corp. EPA Reg. No. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904 Product Name ☐ Check if this is a new address Section - II X Amendment Explain below ☐ Final printed labels in response to Agency letter dated_ □ "Me Too" Application. ☐ Resubmission in response to Agency letter dated_ □ Notification - Explain below. ☐ Other - explain below. Explanation: Use additional page(s) if necessary. (For section I and Section II.) Application for Amendment with Data, Non fast track amendment, EPA # R34, 100% small business waiver requested. Contact name: Cristina Griffin, Agent for Bushwacker Backpack and Supply Company, DBA Counter Assault, email cgriffin@delta-ac.com. Section - III 1. Material this Product will be Packaged In: 2. Type of Container Child Resistant Packaging Unit Packaging Water Soluble Packaging ☐ Yes* ☐ Yes □ Metal ☐ Yes □ No □ No ☐ Plastic □ No ☐ Glass If "Yes," If "Yes," ☐ Paper * Certification must ☐ Other (Specify)_ Unit Package wgt. Unit Package wot. No. per container No. per container be submitted. 3. Location of Net Contents Information 4. Size(s) of Retail Container 5. Location of Label Direction □ On Label On Labeling accompanying product □ Label □ Container 6. Manner In Which Label Is Affixed to Product □ Other __ □ Lithograph ☐ Paper glued☐ Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Telephone No. (Include Area Code) Cristina Griffin Agent for Counter 301-680-7971 Assault 6. Date Application Certification Received I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any kind of knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. Stamped) 2. Signature Agent for Counter Assault 4. Typed Name 5 Date Cristina Griffin February 27, 2007



Dan Peacock/DC/USEPA/US

02/07/2007 09:13 AM

John Hebert/DC/USEPA/US@EPA, Venus To Eagle/DC/USEPA/US@EPA, Meredith Laws/DC/USEPA/US@EPA, Pauline

CC

bcc

55541-2: Results of Meeting to Discuss the Proper Action Code for Amendment to Add New Inert Requiring Efficacy

Subject Dat

Decision 373589, S-803017

Dear All.

Purpose:

This E-Mail communicates the results of an IRB Meeting at about 8:20 AM this morning.

The participants were John Hebert, Venus Eagle, and Dan Peacock

 The purpose of the meeting was to discuss the correct Action Code for an amendment for an a new, nonfood inert, requiring chemistry information and efficacy data.

Problem:

 Initially, the screener gave the action a "345 Action Code" because it involved only the submission of a new CSF and supporting information.

 IIAB personnel (Pauline Wagner and Kerry Leifer) old me last week that 90 days was an insufficient amount of review time for a new, nonfood inert.

We could give the amendment a "R34 Action Code" because the action needed efficacy data.
 However, the company has sent no data.

 The current due date is March 22, 2007, which is insufficient time to complete either a chemistry or efficacy review under either Action Codes 345 or R34.

 We cannot give the amendment "Action Code R23" because such codes are for actions involving new uses of active ingredients, not inert ingredients.

Solution:

 Change the current action code for the amendment from "Action Code 345" to "Action Code 305" to cover the chemistry review and provide a review period > 90 days.

 When the company submits the efficacy data, we will give that submission "Action Code R34" that allows us a 4 month review period.

 Insure that we only make a final decision about the amendment after the company has setisfied both the chemistry and efficacy requirements under the two beans.

Feedback:

 If anyone has feedback about this decision, please contact the above interested parties so that it could be improved in the future. Thank You,

Daniel B. Peacock, Biologist Tel: 703-305-5407 Fax: 703-305-6920 E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202



To Dan Peacock/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US

cc bcc

Subject codes for inert approvals

History:

This message has been replied to.

Dan - I won't be able to make the meeting you scheduled to discuss this issue, I have to prepare for Lois' staff meeting. I read your proposal and need to let you know a couple of things. The PRIA action categories were negotiated with Industry and approved by Congress. They apply to active ingredients and not inerts so we can't just now decide that an R23, for example, would apply to an inert.

PRIA 1 expires in 2009 and PRIA "2" has been sent forward to Congress with proposals from both OPP and Industry. Before it was sent forward we tried to come to agreement with Industry on all the new proposals, theirs and ours. We did not agree on everything. There is a proposed new category for new food use inerts and new nonfood use inerts but I do not know how it will survive the Congressional review. I also do not know what time frames or fees will be applied.

I agree that the product with the new inert should not have received a 345 but it does not fit any of the current PRIA categories.

Meredith



John Hebert/DC/USEPA/US 02/06/2007 07:57 AM

To Dan Peacock/DC/USEPA/US@EPA

cc Meredith Laws/DC/USEPA/US@EPA

bcc

Subject Re: codes for inert approvals

You can give the application to me and I'll get the code changed and a PRIA invoice issued.

John

Dan Peacock/DC/USEPA/US



Dan Peacock/DC/USEPA/US 02/06/2007 06:50 AM

To Meredith Laws/DC/USEPA/US@EPA

cc John Hebert/DC/USEPA/US@EPA

Subject Re: codes for inert approvals

Meredith,

Given that history, my suggestion would be the following:

 insure that if new, non-food inert amendment actions are associated with review of other non-food data (acute tox/efficacy), the action receives the PRIA code [For 55541-2, it would be R34, not 345.]
 For some new inerts, some tox data might be required anyway.

Daniel B. Peacock, Biologist

Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

Meredith Laws/DC/USEPA/US

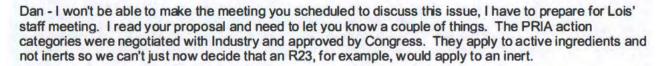


Meredith Lawa/DC/USEPA/US 02/05/2007 04:41 PM

To Dan Peacock/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US

œ

Subject codes for inert approvals



PRIA 1 expires in 2009 and PRIA "2" has been sent forward to Congress with proposals from both OPP and Industry. Before it was sent forward we tried to come to agreement with Industry on all the new proposals, theirs and ours. We did not agree on everything. There is a proposed new category for new food use inerts and new nonfood use inerts but I do not know how it will survive the Congressional review. I also do not know what time frames or fees will be applied.

I agree that the product with the new inert should not have received a 345 but it does not fit any of the current PRIA categories.

Meredith



Dan Peacock/DC/USEPA/US

02/05/2007 10:35 AM

To cgriffin@delta-ac.com

CC

bcc

Fw: Request for Feedback: List of Registered Bear Deterrent Subject

Products and Visibility of Labeling at Point of Sale

Dear Christina,

I found your October 23, 2006, letter that outlined the visibility problem.

I could not find a record of putting the companies "on notice" about the problem.

Therefore, I have sent the 4 registrations the E-Mail below identifying the problem and requesting a response in 30 days.

Hopefully, this will solve the problem. However, if it does not solve the problem, then we will have to have enforcement pick up samples of all products and review the labels, especially the visibility.

Thank you for bringing this problem to my attention.

Thank You,

Daniel B. Peacock, Biologist

Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

---- Forwarded by Dan Peacock/DC/USEPA/US on 02/05/2007 10:27 AM ----



Dan Peacock/DC/USEPA/US

02/05/2007 10:26 AM

To counterassault@bigsky.net, randy@guardalaska.com, pepperpower@udap.com, info@sabre-sabrered.com

CC

Request for Feedback: List of Registered Bear Deterrent Products and Visibility of Labeling at Point of Sale

Dear Registrants of Bear Deterrent Products,

I have two topics to bring to your attention today.

However, before discussing these topics, I wanted to thank each of you for working with me over the past 10 years to provide registered bear deterrent products to the market and thereby provide the users of such products with the best opportunity of surviving a human-bear encounter. By working together, we have avoided a situation where the lack of regulation would have resulted unfortunate consequences.

Topic 1 Update to List of Bear Deterrent Products in the US

Background:

Over the past many years, EPA Region 8 has posted a list of "Registered Bear Deterrent Products in United States".

This part of EPA's "Public Education Program" insures that potential users of such products know which ones EPA had registered and how to obtain additional information about the products.

I last updated this list on June 20, 2006.



Registered Bear Deterrent Products in United States, June 2006.doc

Request:

Within the next 30 days, please indicate any changes that you would like to see in the next version.

Topic 2 Visibility of Labeling at Point of Sale

Background:

Registrants often sell their products in clamshell packaging and need to be aware of a labeling requirement in the Code of Federal Regulations, 40 CFR 156(a)(4)(i), that:

If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

Request:

Within the next 30 days, please review all of your packaging presentations, especially those in clamshell package for visibility, and reply with the results of your review.

Specifically, do you have any problems with the visibility on any text of any panel? Can a person easily read the entire text of the label without opening the outer wrapper or clamshell? If not, a) what specific text is obscured and b) how would you propose to solve the visibility problem, such as:

- repeat the obscured text on the back of the card;
- 2. repeat the obscured text on a card between back of the can and the plastic, or
- adhering the obscured text to the outside wrapper.

The goal is to allow the potential buyer to review the entire text of the can label prior to purchase.

Please indicate when you would be able to begin using the new packaging, not to exceed 12 months (March 1, 2006).

If you have any questions about this E-Mail, please contact me.

Thank You,

Daniel B. Peacock, Biologist Tel: 703-305-5407 Fax: 703-305-6920 E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202



Dan Peacock/DC/USEPA/US 02/05/2007 10:26 AM To counterassault@bigsky.net, randy@guardalaska.com, pepperpower@udap.com, info@sabre-sabrered.com

boo

-

Subject Request for Feedback: List of Registered Bear Deterrent Products and Visibility of Labeling at Point of Sale

Dear Registrants of Bear Deterrent Products,

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- repeat the obscured text on the back of the card;
- 2. repeat the obscured text on a card between back of the can and the plastic, or
- 3. adhering the obscured text to the outside wrapper.

The goal is to allow the potential buyer to review the entire text of the can label prior to purchase.

Please indicate when you would be able to begin using the new packaging, not to exceed 12 months (March 1, 2008).

If you have any questions about this E-Mail, please contact me.

Thank You,

Daniel B. Peacock, Biologist Tel: 703-305-5407 Fax: 703-305-6920 E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

	Registered Bear Deterrent Products in United States ¹² June 20, 2006
No	Product Name, Registration No, Company Contact Information
1	Counter Assault Bear Deterrent EPA Reg. No. 55541-2
	Bushwacker Backpack & Supply Co. Inc., 120 Industry Court
	Kalispell, MT 59901, Attention: Mr. Pride Johnson
	Tel: 1-800-695-3394
	E-Mail: counterassault@bigsky.net; Web Site: counterassault.com/
2	Guard Alaska Bear Repellent EPA Reg. No. 71545-1
	McNeil River Enterprises, Inc., 750 West Diamond, Suite 203
	Anchorage, AK 99515, Attention: Mr. Randy Prater
	Tel: 1-888-419-9695
	E-Mail: randy@guardalaska.com; Web Site: guardalaska.com
3	Pepper Power
	EPA Reg. No. 72007-1
	Universal Defense Alternative Products (UDAP)
	13160 Yonder Road
	Bozeman, MT 59715, Attention: Mark Matheny
	Tel: 1-800-232-7941
	E-Mail: pepperpower@udap.com; Website: udap.com
4	Frontiersman Bear Attack Deterrent
	EPA Reg. No. 72265-1 Security Equipment Corp.
	330 Sun Valley Circle
	Fenton, MO 63036, Attention: Mr. Larry Nance
	Tel: 1-636-343-0200
	E-Mail: info@sabre-sabrered.com; Website: sabre-sabrered.com
ocation	Dan Peacock, Flash Drive, 256 mb, F:\Capsaicin\Bear Repellents\Registered Bear Deterrent Products in United States, June 2006.doc

distance, and time to empty can) affect product effectiveness.

¹ In addition to these 4 products, EPA allows "distributor products" that are identical to the above products but have a different name, address, and an additional number to the registration number.

² EPA has no data in its files to show that the differences in the products (such as, amount of active, spray



October 23, 2006

Mr. Dan Peacock (7504P)
EPA Office of Pesticide Programs
1200 Pennsylvania Ave. NW
Washington DC 20460

RE: Bear Deterrents: Clamshell Packaging with Insert Card

Dear Dan:

The purpose of this letter is to discuss the clamshell packaging for bear deterrents and the non compliance of at least one of Counter Assault's competitors with the rules you articulated to Counter Assault. Attached are two e-mail excerpts; the first is your response to Counter Assault's previous consultant, Elizabeth Brown, and the second is Elizabeth Brown's e mail notifying Counter Assault as to the understanding of discussions with you pertaining to the correct labeling on the insert card for clamshell packaging. You noted that bear deterrents are associated with preventing extreme hazards and that all directions need to be clearly visible on the package. You explained that your option 2 would be to print the text, in a least 6 point, on a card that could be slipped into the clamshell between the actual container and plastic.

Counter Assault has waited for over two years while inventories of competitors' non-compliance clamshells were to be eliminated from the market. They assumed that after 18 months the non compliant packaging would disappear. As recently as this past summer and fall, retailers are receiving clamshell products from UDAP that do not comply with the packaging requirements you identified in your August 5, 2004 response to Elizabeth Brown.

Complying with EPA's rules for visible directions puts Counter Assault at a price disadvantage if others do not have to comply with the same rules. Since UDAP's packaging does not ensure that all label text is visible at the point of purchase as required, UDAP can use smaller packaging. The smaller size results in reduced plastic cost, which translates into reduced shipping costs and less shelf space. This clearly puts Counter Assault at a competitive disadvantage.

Counter Assault is requesting that EPA enforce compliance in a swift and decisive manner. If you have any questions, please call me at 301 680-7971. I will call you within a couple of weeks to ascertain next steps.

Sincerely,

Cristina Griffin

Agent for Counter Assault

Attachment: E-mail excerpts

Cc: Pride Johnson, Counter Assault

Attachment

-----E-MAIL ECERPTS FROM 2004

----Original Message -

- > From: Peacock.Dan@epamail.epa.gov [mailto:Peacock.Dan@epamail.epa.gov]
- > Sent: Thursday, August 05, 2004 12:52 PM
- > To: Elizabeth Brown
- > Cc: Hebert.John@epamail.epa.gov
- > Subject: Counter Assault Labeling Issues, EPA Reg. No. 55541-2

Company Request

- > They would like to be able to have packaging close to what UDAP has to
- > address the two issues of increased shipping costs and shelf space.

> EPA Response to Counter Assault

- > To comply with 40 CFR 156.10(a)(4), Counter Assault needs to repeat the
- > texts of their Left and Right Panels on the back of their clam shell
- > label by:

>

- > 1.putting the text on the back of the card and to the left of the can
- > (company's current practice);
- > 2.putting the text of the Left and Right Panels between the back of the
- > can and the plastic; or
- > 3.adhering the text of the Left and Right Panels to the plastic itself.

>

- > Using one of the above options would insure that all labeling was
- > clearly visible, as required, and that the registrant saves the shipping
- > and shelf space costs.

>

- > EPA will inform the other three registrants of these options for product
- > packaged in clamshells and of the need to comply at their next printing.
- Original Message

From: "Elizabeth Brown" <brown@chemreg.com>

To: <pri>counterassault.com>

Sent: Friday, August 06, 2004 6:38 AM

Subject: FW: Counter Assault Labeling Issues, EPA Reg. No. 55541-2

- > Pride and Kirsten:
- > Please call me to discuss the following agreements with EPA. We got most
- > of what you wanted and with a very simple way to accomplish the
- > agreed-upon changes. Providing the actual packages to Dan really helped,
- > and he very much appreciated it. It let him understand both the issues on
- > packaging and identify a way to accomplish what you want to do. Please
- > note that UDAP's package was not considered to be fully acceptable and
- > that UDAP and the other registered products will be getting letters from
- > EPA to revise their packaging in accordance with what he's identified.





E-Mail Message: February 7, 2007, 9:13AM

Subject:

55541-2: Results of Meeting to Discuss the Proper Action Code for Amendment to Add New Inert Requiring Efficacy Data Decision 373589, S-803017

From:

Dan Peacock, Biologist Insecticide-Rodenticide Branch Registration Division

To:

John Hebert/DC/USEPA/US@EPA, Venus Eagle/DC/USEPA/US@EPA, Meredith Laws/DC/USEPA/US@EPA, Pauline Wagner/DC/USEPA/US@EPA, Kerry Leifer/DC/USEPA/US@EPA, Karen Angulo/DC/USEPA/US@EPA

Dear All,

Purpose:

- This E-Mail communicates the results of an IRB Meeting at about 8:20 AM this morning.
- The participants were John Hebert, Venus Eagle, and Dan Peacock
- The purpose of the meeting was to discuss the correct Action Code for an amendment for an a new, nonfood inert, requiring chemistry information and efficacy data.

Problem:

- Initially, the screener gave the action a "345 Action Code" because it involved only the submission of a new CSF and supporting information.
- IIAB personnel (Pauline Wagner and Kerry Leifer) old me last week that 90 days was an
 insufficient amount of review time for a new, nonfood inert.
- We could give the amendment a "R34 Action Code" because the action needed efficacy data. However, the company hes sent no data.
- The current due date is March 22, 2007, which is insufficient time to complete either a chemistry or efficacy review under either Action Codes 345 or R34.
- We cannot give the amendment "Action Code R23" because such codes are for actions involving new uses of active ingredients, not inert ingredients.

Solution:

- Change the current action code for the amendment from "Action Code 345" to "Action Code 305" to cover the chemistry review and provide a review period > 90 days.
- When the company submits the efficacy data, we will give that submission "Action Code R34" that allows us a 4 month review period.
- Insure that we only make a final decision about the amendment after the company has satisfied both the chemistry and efficacy requirements under the two beans.

Feedback:

 If anyone has feedback about this decision, please contact the above interested parties so that it could be improved in the future.

Thank You,

Daniel B. Peacock, Biologist

Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Location:

Dan Peacock, Flash Drive, 1gb, K:\Capsaicin\55541-2, Codes for New Nonfood Inert - Efficacy Data, 2-7-2007.doc

February 2, 2007

MEMORANDUM

Subject Need to Assign Different OPPIN Codes for Actions to Add New,

Non-Food Inerts

Counter Assault Bear Deterrent

EPA Reg. No. 55541-2

Review of Amended Application

Daniel B. Peacock, Biologist
Insecticide-Rodenticide Box From

Insecticide-Rodenticide Branch

To Meredith Laws, Chief

Insecticide-Rodenticide Branch

Purpose This memorandum suggests that we assign different OPPIN Codes ("R23,

R24, R26, or R27" instead of "345") for actions to add new, non-food

inerts to the Agency's list of inerts.

Background I recently received an application for a new, non-food inert.

The incoming package clearly described the purpose of the action.

The "Screening Group" assigned it Action Code 345.

 Prior to submission, Karen Angulo of IIAB had provided extensive help to the submitter about the contents of the package.

Prior to submission, the submitter informed me about an alternate formulation, but not that an inert would be new for the Agency.

Problem

I discussed the action code with Pauline Wagner and Kerry Leifer. They felt that the amount of resources needed to review such an action was far greater than that needed for a typical "345" action¹. However, they did not know what action to assign.

- They thought that this action was a good one to use to identify the problem as EPA should expect many similar requests in the future.
- IIAB also wants to develop a procedure for handling such actions.
- I promised to bring the problem to your attention.

For the specific action that triggered this discussion, the proper action code would at least be R34 as it involves review of efficacy data. However, that change does not address the question of how to assign an action code reflecting the chemistry portion of the resources needed to review a new, non-food inert.

Discussion

- The current assignment of Action Code 345 (simple chemistry changes) to the review of new, non-food inerts (review of extensive chemistry data or public literature sources and perhaps extensive internal reviews and FR publication) doesn't reflect the resources.
- Action Code 270 is also inappropriate since that code is one for review of new, food use inerts and associated tolerances.
- Using codes such as R34 may reflect resources for acute toxicity or efficacy but do not reflect the chemistry resources needed.
- Using codes normally reserved for HED and EFED reviews of new uses would reflect the time and resources needed to review the chemistry for a new, non-food inert until better codes could be incorporated into a revised PRIA, if needed.
- If the amounts of money normally required for such HED/EFED
 codes are too much for the review of a new, nonfood inert, then
 EPA could refund part of the fee, just as it refunds part of a fee now
 for other reasons.

Suggestion

- I would suggest that, for actions to review a new, non-food inert, we assign one of the following PRIA codes:
- 1. R23, New Use, Non-Food, Outdoor, 15 months, \$21,000,
- R24, New Use, Non-Food, Outdoor, Reduced Risk, 12 months, \$21,000
- 3. R26, New Use, Non-Food, Indoor, 12 months, \$10,500, or
- R27, New Use, Non-Food, Indoor, 9 months, Reduced Risk, \$10, 000.
- The rationale for calling the action a "new use" would be that "for the inert", its first approved use would be "new".

Dan Peacock, Flash Drive, 1gmb, K:\Capsaicin\55541-2, Need to Assign Different Action Codes - New NonFood Inert, 2-2-2007.doc



TracyH Ward/DC/USEPA/US 04/20/2007 10:37 AM

To Dan Peacock/DC/USEPA/US@EPA, Pauline Wagner/DC/USEPA/US@EPA

cc Mary Frankenberry/DC/USEPA/US@EPA

bcc

Subject Inert Ingredient

Dan,

After further discussion with OGC's Michele Knorr-we've found that it would not be practical to try limiting for non-food uses. Because it is highly toxic to aquatic organisms and persistant in the environment, we cannot make the FIFRA safety findings for the use of this chemical as a non-food use inert ingredient.

Please contact me if you have any questions. I'll return the data package to you and close the bean in OPPIN.

Thank you,

TracyH Ward, Biologist Inert Ingredient Assessment Branch EPA/OPPTS/OPP/Registration Division (7505P) Phone: (703) 308-9361

Inert ingredient information may be entitled to confidential treatment



Dan Peacock/DC/USEPA/US 02/02/2007 01:39 PM To John Hebert/DC/USEPA/US@EPA

cc Venus Eagle/DC/USEPA/US@EPA

bcc

Subject Proposed Meeting on Wed, PRIA Codes

John.

Though Meredith is unable to attend the proposed meeting, we (Venus, you, and I) can still meet and talk/brainstorm a bit on the question of
the proper action codes for new, non-food inerts at the proposed meeting time and place.

At that point, I think that I have discharged my responsibility. Then it is up to those who determine and assign codes to work with IIAB and
others to find a solution to this problem.

Would you agree?

Thank You,

Daniel B. Peacock, Biologist

Tel: 703-305-5407 Fax: 703-305-6920

E-Mail: peacock.dan@epa.gov

Addresses:

United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

December 28, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CRISTINIA GRIFFIN/JEFF JONES
DELTA ANALYTICAL CORPORATION
BUSHWACKER BACKPACK & SUPPLY CO.
12510 PROSPERITY DRIVE, SUITE 160
SILVER SPRING, MA 20904-

PRODUCT NAME: COUNTER ASSAULT BEAR DETERRENT COMPANY NAME: BUSHWACKER BACKPACK & SUPPLY CO.

OPP IDENTIFICATION NUMBER: 306441

EPA FILE SYMBOL: 55541-2 EPA RECEIPT DATE: 12/22/06

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 7, at (703) 308-6249.

Sincerely,

7 wrice

Front End Processing Staff Information Services Branch

Information Technology & Resources Management Division

Fee for Service

{803017Â~

This package includes the following	for Division			
New Registration Amendment	○ AD ○ BPPD ○ RD			
□ Studies? □ Fee Waiver? □ volpay % Reduction:	Risk Mgr. 7			
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	803017 55541-2 12/22/2006			
This item is NOT subject to	FFS action.			
Action Code: Requested: Granted: Amount Due: \$	Parent/Child Decisions:			

NON - FEE









United States

Environmental Protection Agency

☐ Registration X Amendment

OPP Identifier Number

W EPA			Washington DC 20460		dment	306441	
		Application for Pe	esticide - Section I				
1. Company/Product Number 55541-2			2 EPA Product Manager John Hebert	John Hebert		Proposed Classification	
4. Company/Product (Name) Count Bear Deterrent	РМ# 7		Line	LI NOSULIO			
5. Name and Address of Applicant (Incl. Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Drive, Su Silver Spring, MD 20904 Check if this is a new address	Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPAReg. No Product Name						
		Sect	ion - II				
X Amendment - Explain below Resubmission in response to Agency Notification - Explain below.	☐ Final printed labels in response to Agency letter dated "Me Too" Application. ☐ Other - explain below.						
Explanation: Use additional page(s) if CSF amendment to add no New inert ingredient subm	w inert ingre						
		Secti	on - III				
Material this Product will be Pack	aged in:						
Child-Resistant Packaging Unit Packaging Yes* Yes		ng	Water Soluble Packaging ☐ Yes ☐ No		2. Type of Container Metal Plastic		
* Certification must be submitted.	If "Yes," Unit Package	a wgt. No. per container	If "Yes," Unit Package wgt. No. per container		☐ Glass ☐ Paper ☐ Other (Specify)		
Location of Net Contents Information Label			5. Location of Label Direction On Label On Labeling accompa				
6. Manner In Which Label Is Affixed to	Product	☐ Lithograph☐ Paper glued☐ Stenciled	☐ Other				
		Secti	on - IV	_			
Contact Point (Complete items direct	tly below for identif	ication of individual to be cont	acted, if necessary, to process	s this applicatio	n.)		
Name Cristina Griffin			Agent for Counte			lo. (Igclude Area Code)	
I certify that the statements I have mad			ue, accurate and complete. I a	acknowledge th	at any kipd	6. Date Application Received	
of knowingly false or misleading statement may be punishable by fine or imprisonment 2. Signature			3. Title Agent for Counter Assault			(Stamped)	
4. Typed Name Cristina Griffin			5. Date December 20, 2006				



United States

₩ EPA		Environmental Protection Agency Washington, DC 20460		X Amen	dment	306441	
•		Application for Pe	esticide - Section I				
1. Company/Product Number 55541-2			2. EPA Product Manager John Hebert		3. Proposed Classification □ None □ Restricted		
4. Company/Product (Name) Counter Assault / Counter Assault Bear Deterrent			РМ#7		Difference Difference		
5. Name and Address of Applicant (Incl Counter Assault c/o Delta Analytical Corp. 12510 Prosperity Drive, Su Silver Spring, MD 20904 Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name						
		Secti	ion - II				
X Amendment - Explain below Resubmission in response to Agency Notification - Explain below.	☐ Final printed labels In response to Agency letter dated						
Explanation: Use additional page(s) if CSF amendment to add ne New inert ingredient subm	w inert ingre						
		Secti	on - III				
1. Material this Product will be Pack	aged in:						
Child-Resistant Packaging Yes*	Unit Packaging ☐ Yes ☐ No		Water Soluble Packaging ☐ Yes ☐ No		2. Type of Container		
* Certification must be submitted.	if "Yes," Unit Package	wgt. No. per container	if "Yes," Unit Package wgt. No. s	per container	☐ Glass ☐ Paper ☐ Other (Specify)		
Location of Net Contents Information Label			5. Location of Label Direction On Label On Label On Labeling accompar				
6. Manner in Which Label Is Affixed to I	Product	☐ Lithograph ☐ Paper glued ☐ Stenciled	☐ Other				
		Section	on - IV				
1. Contact Point (Complete items direct	ly below for identit	ication of individual to be cont	acted, if necessary, to process	s this application	n.)		
Name Cristina Griffin			Agent for Counte			o. (Igclude Area Code)	
I certify that the statements I have made of knowingly false or misleading statem			ue, accurate and complete. I a	scknowledge th	atany kipd	6. Date Application Received	
2. Signeture Littura L.			3. Title Agent for Counter Assault			(Stamped)	
4. Typed Name Cristina Griffin			5. Date December 20, 2006			****	